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ORIGINAL ARTICLE

- An Observational Randomized Comparative Study to Assess Surgical Management of Varicose Vein with and without Venous Stripping
- Assessment of Knowledge and Practice Regarding Pediatric Drug Administration Among Staff Nurses
- A Comparative Study of Right Shoulder Tip Pain in Low Versus Standard Pressure CO_2 Pneumoperitoneum in Laparoscopic Cholecystectomy
- A Descriptive study of Adverse Drug Reactions with Causality Assessment and Potential Drug-Drug Interactions in the Outpatients of the Psychiatric Department at SMS Hospital, Jaipur, Rajasthan
- A Descriptive Study of Prescription Pattern in Pregnant Women attending Antenatal Clinic of Department of Obstetrics and Gynaecology in SMS Hospital, Jaipur, Rajasthan
- A Descriptive Observational Study on the Evaluation of Antihypertensive Medications as Fall Risk Increasing Drugs in Elderly Patients Presenting with Injurious Falls at a Tertiary Care Teaching Hospital
- An Observational Study to Determine the Efficacy of Small Tissue Bite Fascial Closure over Regular Tissue Bite Fascial Closure in Prevention of Surgical Site Infections and Wound Dehiscence in Midline Laparotomies
- Effectiveness of 3-Day Prophylactic Negative Pressure Wound Therapy versus Conventional Dressing on Closed Abdominal Incisions: An Observational Study
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CASE REPORT

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Original Article

An Observational Randomized Comparative Study to Assess Surgical Management of Varicose Vein with and without Venous Stripping

Shubham Khatri*, Amit Goyal*, Rohit Gupta*

ABSTRACT

Background: Varicose veins, characterized by dilated, tortuous, and elongated superficial veins—most commonly involving the great saphenous vein (GSV)-result primarily from incompetence of venous valves and Saphenofemoral-Junction. Traditional surgical approach include Trendelenburg's procedure followed by venous stripping. Despite growing body of evidence supporting Trendelenburg's procedure without venous stripping, surgical community still lacks consensus on ideal approach.

Method: Study comprise of 60 patients with varicose veins allocated into two groups of 30 each where they underwent Trendelenburg's procedure with or without stripping of varicose vein. Patients were followed up for three months to assess efficacy of the procedure as per parameters of the study. Data analysis performed using SPSS software.

Result: In the group undergoing stripping, 20% patients developed hematoma, post operative pain scores on day 0,3 and 7 were 4.17±1.32, 2.43±0.8 and 1.23±0.67 respectively. Mean post operative ambulation was achieved on 3.33 days and recurrence at 3 months was seen in 0% patients. In the group undergoing ligation alone, 6.67% patients developed hematoma, post operative pain scores on day 0,3 and 7 were 3.13±1.09, 1.6±0.84 and 0.8±0.54 respectively. Mean post op ambulation was achieved on 2.23 days and recurrence at 3 months was seen in 6.67% patients.

Conclusion: With lesser rates of hematoma formation, better post operative pain scores and quicker ambulation in patients undergong ligation of veins alone, we conclude that Trendelenberg's procedure without stripping is a better procedure than with stripping.

Keywords: Varicose veins, Trendelenberg's procedure, Stripping of veins.

INTRODUCTION

Varicose veins are a prevalent and chronic venous disorder that significantly impact both the physical and psychological well-being of affected individuals. Characterized by dilated, tortuous, and elongated superficial veins—most commonly involving the great saphenous vein (GSV)—they result primarily from incompetence of venous valves and resultant retrograde blood flow. This leads to increased venous pressure, dilation, and further valve failure.1 The prevalence of varicose veins varies widely across populations, with studies indicating a range between 10% to 40% in the general adult population. The condition is more common in women, older individuals, and those with occupational histories involving prolonged standing, obesity, sedentary lifestyles, and genetic predispositions. While many consider varicose veins a cosmetic concern, they often lead to significant symptoms such as leg heaviness, aching pain, fatigue, ankle swelling, night cramps, skin discoloration, eczema, and, in severe cases, venous ulcers. When left untreated, varicose veins can progress to chronic venous insufficiency (CVI), which is associated with complications like thrombophlebitis, persistent ulceration, and haemorrhage, ultimately reducing the quality of life and increasing healthcare burden.[2,3]

The pathophysiology of varicose veins lies in the dysfunction of venous valves, particularly at the saphenofemoral and saphenopopliteal junctions. When these valves fail to maintain unidirectional flow, it results in blood pooling within the superficial venous system, leading to progressive venous hypertension. Over time, this causes the veins to become dilated and twisted, further impairing their function. The CEAP classification (Clinical, Etiologic, Anatomic, Pathophysiologic) system has been developed to categorize venous disorders, aiding in diagnosis, treatment planning, and outcome assessment.[4,5]

A Surgical management remains a cornerstone of treatment, particularly for patients with symptomatic or complicated varicose veins. Traditional surgical approaches include high ligation of the saphenofemoral junction—commonly known as the Trendelenburg procedure—followed by stripping of the great saphenous vein and multiple stab avulsions of tributaries. The Trendelenburg operation involves ligating the GSV flush at its junction with the femoral vein, thereby eliminating the main source of reflux. Vein stripping, usually extending from the groin to below the knee, ensures that

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the refluxing segment of the GSV is physically removed, which is believed to reduce recurrence. However, stripping is not without complications. Patients often experience postoperative hematomas, bruising, saphenous nerve injury, and delayed wound healing. In contrast, limiting the procedure to flush ligation without stripping has been proposed as a less invasive alternative with fewer postoperative complications.[6,7]

The advantages of avoiding venous stripping during Trendelenburg procedure are increasingly being recognized. These include reduced intraoperative bleeding, less postoperative pain, lower rates of hematoma and infection, and shorter convalescence. Furthermore, avoidance of stripping preserves the GSV for future vascular access or coronary bypass grafting, which can be valuable in elderly or high-risk cardiovascular patients. Additionally, early ambulation in patients who have undergone ligation-only surgery lowers the risk of postoperative deep vein thrombosis, further contributing to improved safety outcomes. Given the significant overlap in therapeutic benefit but marked difference in complication rates, it is essential to explore whether GSV stripping is always necessary in the surgical management of varicose veins.[1]

Despite the growing body of evidence supporting ligation-only procedures, the surgical community still lacks consensus on the ideal approach. Most existing studies have either small sample sizes or lack comprehensive evaluation of parameters like pain, ambulation, wound healing, and cost-effectiveness in a randomized observational framework. Therefore, the present study aims to conduct a robust observational randomized comparative analysis of Trendelenburg procedure with and without venous stripping, specifically assessing short-term and intermediate outcomes.

METHODS

Aim and Objective of the study: To compare outcome of Trendelenberg's procedure for varicose vein with and without venous stripping with respect to

1. To assess post operative pain on day 0, 3 and 7.
2. To assess Hernatoma formation.
3. To determine day of comfortable ambulation.
4. To assess the recurrence after 3 months of Trendelenburg's procedure with and without venous stripping.

Methodology

The study was conducted in the Department of General Surgery at S.M.S. Medical College and Hospital, Jaipur, a tertiary care center serving a wide range of urban and rural patients. This was a hospital-based, prospective, comparative study. The study was carried out after obtaining approval from the Institutional Ethics Committee and continued until December 2024. The study include all patients diagnosed with varicose veins and admitted to the Department of General Surgery, S.M.S. Hospital, Jaipur, during the study period.

Inclusion Criteria

1. Patients aged between 18 and 60 years.
2. Patients willing to provide written informed consent.
3. Patients presenting with tortuous and dilated veins (>3 mm) of the lower limb associated with saphenofemoral junction incompetence and perforator incompetence.

Exclusion Criteria

1. Patients diagnosed with deep vein thrombosis (DVT).
2. Patients with secondary varicose veins (e.g., post-thrombotic syndrome, pelvic mass, or arteriovenous fistula).

Sample Size

According to study conducted by Lamani et al[8] in 2021, The sample size was determined based on the primary outcome variable—postoperative pain on day 3. Referring to the seed article, a minimum detectable mean difference of 1 unit with a standard deviation of 0.8 was used for the calculation. Using the formula:

$$n = \frac{\left(Z\,{}^{\alpha}/_{2} + Z\beta\right)^2}{d^2} \times \sigma^2$$

- $Z\alpha/2=1.96$ for 95% confidence level ($\alpha = 0.05$)
- $Z\beta=0.84$ for 80% power ($\beta = 0.20$)
- $d=1$ (minimum detectable difference)
- $\sigma=0.8$ (standard deviation)

The calculated sample size was 30 patients per group, making a total of 60 participants.

Randomisation

Participants were randomly allocated into two groups using a simple randomisation technique, wherein every alternate eligible patient was assigned to either the group undergoing Trendelenburg procedure with venous stripping or the group undergoing the procedure without stripping.

Data Collection Procedure

All patients included in the study underwent Trendelenburg's procedure in the Department of General Surgery at S.M.S. Medical College and Hospital, Jaipur. Preoperative demographic and clinical data were recorded.

Postoperative assessment and outcome variables

1. **Pain Evaluation:** Postoperative pain was assessed using the Wong-Baker Visual Analog Scale (VAS) on the evening of the surgery (Postoperative Day 0), and subsequently on Postoperative Day 3 and Day 7.
2. **Hematoma Formation:** Clinical examination for thigh hematoma was conducted on Postoperative Day 3.
3. **Ambulation Assessment:** Patients were encouraged to begin ambulating with compression

stockings starting from Postoperative Day 1. The first day on which the patient was able to walk comfortably was recorded.

4. **Recurrence Monitoring:** Patients were followed up for a period of three months postoperatively to assess for recurrence of varicose veins, either clinically or with Doppler ultrasonography, if indicated.

Statistical analysis

Data analysis was performed using SPSS software. Descriptive statistics such as percentages and proportions were used for qualitative variables, while means and standard deviations were calculated for quantitative variables. Inferential statistics, including the Chi-square test for categorical variables and the Student's t-test for continuous variables, were applied to compare outcomes between the two groups. A p-value of less than 0.05 was considered statistically significant.

RESULTS

In this study, the age group 41-50 years formed the majority of sample size at 53.33% followed by 31-40 years with 18.33% and 51-60 years with 16.66% representation in the sample size.

Male patients formed the bulk of the study population with 40 out of 60 patients being male, constituting 66.66% of the sample size.

The left leg was more commonly involved 60% when compared to the right=40%. In Group A right and left limbs were involved in 13 and 17 patients respectively. In Group B right and left limbs were involved in 11 and 19 patients respectively.

Table 1 presents the Visual Analogue Scale (VAS) scores for pain assessment in Group A and Group B at different postoperative time points. On day 0, Group A reported a higher mean pain score (4.17 ± 1.32) compared to Group B (3.13 ± 1.09), with a statistically significant difference (p = 0.002). By day 3, the pain scores decreased in both groups, but Group B continued to show significantly lower pain (1.60 ± 0.84) than Group A (2.43 ± 0.80), with a p-value of 0.001. By day 7, pain levels further declined in both groups, and although Group B still reported slightly lower pain (0.80 ± 0.54 vs. 1.23 ± 0.67), the difference was not statistically significant (p = 0.112). These findings suggest better early postoperative pain control in Group B.

Table 2 presents incidence of postoperative hematoma was higher in Group A (with stripping), where 20% of patients developed hematoma, compared to only 6.67% in Group B (without stripping). Hematoma was absent in 80% of patients in Group A and in 93.33% of patients in Group B. The difference between the two groups was statistically significant, with a p-value of 0.01, indicating a higher likelihood of hematoma formation in patients who underwent stripping.(Table)

Table 3 illustrates the postoperative ambulation timeline for patients in Group A and Group B. In Group A, none of the patients ambulated on day 1, while 3 (10%) began on day 2, 14 (46.67%) on day 3, and 13 (43.33%) on day 4. In contrast, Group B showed earlier ambulation: 3 patients (10%) on day 1, 17 (56.67%) on day 2, and 10 (33.33%) on day 3, with no patients ambulating as late as day 4. The mean number of days to ambulation was significantly shorter in Group B (2.23 ± 0.61 days) compared to Group A (3.33 ± 0.65 days), with a statistically significant p-value of 0.02, suggesting faster recovery in Group B.

Table 4 presents data on the recurrence of a condition at 3 months post-treatment in two groups of patients. In Group A, all 30 patients (100%) showed no recurrence, while in Group B, 28 patients (93.33%) had no recurrence and 2 patients (6.67%) experienced a recurrence. Each group consisted of 30 patients in total, indicating a slightly higher recurrence rate in Group B compared to Group A.

Table 1: Postoperative VAS Scores Over 10 Days in Group A (With Stripping) vs Group B (Without Stripping)

VAS Scores	Number of Patients (%)		P-Value
	Group A	Group B	
VAS at 0 Day	4.17 ± 1.32	3.13 ± 1.09	0.002
VAS at 3 Day	2.43 ± 0.80	1.60 ± 0.84	0.001
VAS at 7 Day	1.23 ± 0.67	0.80 ± 0.54	0.112

Table 2: Incidence of Hematoma in Group A (With Stripping) vs Group B (Without Stripping)

Hematoma	Number of Patients (%)	
	Group A	Group B
Absent	24 (80.00)	28 (93.33)
Present	6 (20.00)	2 (6.67)
Total Patients	30	30
P-Value	0.01	

Table 3: Postoperative Ambulation Timeline in Group A (With Stripping) vs Group B (Without Stripping)

Post Operative Ambulation	Number of Patients (%)	
	Group A	Group B
1 Day	0	3 (10.00)
2 Days	3 (10.00)	17 (56.67)
3 Days	14 (46.67)	10 (33.33)
4 Days	13 (43.33)	0
Total Patients	30	30
No of Days Mean ± SD	3.33 ± 0.65	2.23 ± 0.61
P-Value	0.02	

Table 4: Recurrence at 3 Months in Group A (With Stripping) vs Group B (Without Stripping)

Recurrence at 3 Months	Number of Patients (%)	
	Group A	Group B
Absent	30 (100.00)	28 (93.33)
Present	0	2 (6.67)
Total Patients	30	30

DISCUSSION

Varicose veins represent a prevalent venous disorder exerting a significant impact not only cosmetically but also on physical and psychological well-being. Surgical interventions, particularly the Trendelenburg procedure with or without stripping of the great saphenous vein (GSV), are commonly performed to manage this condition. This study compared clinical outcomes of these two techniques, focusing on postoperative pain, ambulation, hematoma formation, and early recurrence.

In the present study, the age distribution of patients undergoing Trendelenburg's procedure with and without venous stripping was well-matched, with the majority of participants in both groups falling within the 41–50 year age bracket (53.33%). The mean age was 41.87 ± 9.82 years in Group A and 43.77 ± 8.47 years in Group B. The lack of statistically significant difference ($p > 0.05$) indicates that age did not act as a confounding factor affecting postoperative outcomes such as pain, hematoma formation, ambulation, or recurrence. This age trend aligns with findings from a population-based study by Beebe-Dimmer et al. (2005), which reported the peak prevalence of varicose veins in the 40–60 year age range, suggesting that middle age is the period of highest disease burden.[9]

In the present study, the gender distribution revealed a predominance of male patients in both groups. Specifically, in Group A (Trendelenburg's procedure with stripping), 63.33% were male and 36.67% were female, while in Group B (without stripping), 70.00% were male and 30.00% were female. Although there was a slight difference in male predominance between the two groups, this difference was not statistically significant ($p > 0.05$), indicating that gender distribution was comparable between the two groups and unlikely to influence postoperative outcomes such as pain, hematoma, ambulation, or recurrence. The higher male prevalence in this study is consistent with some earlier reports that have shown an increased incidence of clinically significant varicose veins among men, particularly when hospital-based surgical cases are considered. Beebe-Dimmer et al. (2005) reported that while the overall prevalence of varicose veins may be slightly higher in women, the proportion of men undergoing surgical interventions tends to be greater, likely due to delayed care-seeking behavior in males leading to more severe disease at presentation.[47] A recent population study by Zhang et al. (2023) from China also observed a slightly higher surgical intervention rate among male patients, supporting the present findings.[10]

Regarding the laterality of varicose vein involvement, our study demonstrated a slightly higher prevalence of left leg involvement in both groups. In Group A, 56.67% had left leg involvement, while in Group B, 63.33% had left leg disease. This finding is in line with the general anatomical predisposition to left-sided venous disease due to factors such as compression of the left common iliac vein by the overlying right common iliac artery (May-Thurner Syndrome), which has been reported to increase venous pressure and the likelihood of varicosity development on the left side. This anatomical variant may explain the predominance of left-sided disease observed in this study. Similar observations have been documented in earlier research. Caggiati et al. (2002) and Labropoulos et al. (2005) both highlighted the propensity for left-sided varicose vein development due to anatomical and hemodynamic factors, supporting our study's results.[11,12]

Postoperative Pain

In the present study, patients who underwent Trendelenburg's procedure with GSV stripping (Group A) reported significantly higher postoperative pain scores on day 0 and day 3 compared to those who underwent the procedure without stripping (Group B). This difference suggests that vein stripping adds to surgical trauma and subsequent nociceptive stimulation. These findings are corroborated by **Barwell et al. (2004)** who noted that GSV stripping was associated with higher pain scores and delayed return to normal activities compared to less invasive techniques.[13] Similarly, **Neumayer et al. (2003)**demonstrated that the extent of tissue dissection during vein stripping directly correlated with increased postoperative discomfort.[14] This suggests that omitting vein stripping may substantially reduce early postoperative pain, improving patient comfort.

Early Postoperative Ambulation

Early ambulation is crucial for minimizing complications such as venous thromboembolism and promoting faster functional recovery. In this study, the mean time to ambulation was significantly shorter in Group B (2.23 ± 0.61 days) compared to Group A (3.33 ± 0.65 days), with a p-value of 0.02, indicating that the omission of vein stripping facilitates earlier mobility. **Bountouroglou et al. (2006)** reported quicker return to daily routines among patients treated without stripping, owing to reduced postoperative pain and tissue trauma.[15] These observations reinforce the superiority of non-stripping approaches in enhancing early functional outcomes.

Hematoma Formation

Hematoma is a recognized complication of varicose vein surgery, often resulting from excessive manipulation of the venous structures. In this study, Group A had a significantly higher incidence of postoperative hematoma (20%) compared to Group B (6.67%), with a statistically significant difference (p=0.01). This suggests that vein stripping predisposes to greater subcutaneous bleeding. **Rasmussen et al. (2007)** found that the invasiveness of the stripping procedure led to more postoperative bruising and hematoma formation than non-stripping interventions.[16] **Luebke et al. (2008)** further supported this by showing higher wound complication rates, including hematomas, following traditional stripping compared to radiofrequency ablation.[17] Collectively, these studies highlight the advantage of non-stripping procedures in reducing the risk of hematoma and enhancing the postoperative cosmetic outcome.

Recurrence Rate

The present study observed a recurrence rate of 6.67% in Group B (non-stripping) and 0% in Group A (stripping) at 3 months follow-up, although this difference was not statistically significant. This may indicate a potential protective effect of stripping against early recurrence, possibly by removing incompetent venous segments entirely.

This observation is in agreement with the long-term study by **Luebke et al. (2008)** who demonstrated a lower recurrence rate in patients undergoing vein stripping compared to endovenous methods in the early postoperative period.[17] Similarly, **Rasmussen et al. (2011)** noted that anatomical failure and reflux persistence were slightly more frequent in patients treated without stripping, suggesting that removal of the vein may provide superior early anatomical results.[18]

CONCLUSION

The present study demonstrates that while both the Trendelenburg procedure with and without stripping are effective in managing varicose veins, certain advantages were noted with the non-stripping technique. Patients in the non-stripping group experienced significantly less postoperative pain, quicker ambulation, and a lower incidence of hematoma formation. However, a marginally higher recurrence rate was seen in the non-stripping group at the 3-month follow-up. Despite this, the short-term postoperative benefits of avoiding vein stripping suggest that the less invasive approach may be preferable for certain patient populations, particularly when early recovery and reduced postoperative discomfort are priorities. Long-term follow-up is recommended to assess the sustainability of these outcomes.

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Availability of data and materials

Data will be available by emailing skhatri173@gmail.com

Authors' Contributions

- Shubham Khatri: corresponding author participated in data collection, writing, reviewing, and editing.
- Amit Goyal: participated in the investigation, conceptualization, methodology, resources, supervision, validation, writing, reviewing, and editing.
- Rohit Gupta: participated in the investigation, conceptualization, writing, review, data collection, and editing.

All authors have read and agreed to the published version of the manuscript. All authors have read the final manuscript.

Ethics approval and consent to participate

The research adhered to the ethical principles outlined in the Declaration of Helsinki (2013). Approval for the study protocol was granted by the Office of Ethics Committee, S.M.S. Medical college and attached Hospitals, Jaipur, with a decision number of 11 in 2024. Electronic signatures were obtained as informed consent from all individual participants involved in the study. Every procedure conducted during the study complied with the standards of Office of Ethics Committee, S.M.S. Medical college and attached Hospitals, Jaipur and aligned with the principles set forth in the 1964 Helsinki Declaration, along with its subsequent amendments.

Competing Interest

The authors declare that they have no competing interests.

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Original Article

Assessment of Knowledge and Practice Regarding Pediatric Drug Administration Among Staff Nurses

Anju Kumari*, Mahesh Vijaye**

ABSTRACT

Background: Pediatric drug administration requires precise knowledge and careful practice due to the unique physiological characteristics of children. Nurses play a critical role in ensuring medication safety; however, errors in pediatric medication remain prevalent, often linked to gaps in knowledge and practice.

Method: A descriptive cross-sectional study was conducted among 100 staff nurses using a structured questionnaire. Data were analyzed using descriptive and inferential statistics, including mean, standard deviation, chi-square tests, and Pearson correlation.

Result: The majority of staff nurses (49%) had inadequate knowledge, and 54% exhibited unsatisfactory practice related to pediatric drug administration. The mean knowledge score was 14.67 (SD = 6.08), and the mean practice score was 18.85 (SD = 6.90). Significant associations were observed between knowledge/practice scores and variables such as age, educational qualification, total nursing experience, and pediatric ward experience ($p < 0.05$). A strong positive correlation ($r = 0.806$, $p < 0.05$) was found between knowledge and practice.

Conclusion: This study highlights critical deficiencies in nurses' knowledge and practice concerning pediatric drug administration. These findings underscore the need for targeted education, clinical training, and supportive policies to enhance medication safety in pediatric settings.

Keywords: Pediatric nursing, drug administration, knowledge, practice, medication errors, staff nurses, correlation, education.

INTRODUCTION

Safe medication administration is a critical component of pediatric nursing, where even small errors can have severe consequences due to children's physiological vulnerabilities. Pediatric patients are particularly susceptible to medication errors because of their developing organ systems, smaller body sizes, and the complexity of drug dosage calculations, all of which require precise nursing knowledge and attentiveness. Nurses, as the final checkpoint in the medication administration process, play a pivotal role in ensuring pediatric drug safety.

Numerous studies indicate that many medication errors occur at the administration stage, often due to insufficient pharmacological knowledge or lapses in nursing practice. For instance, a cross-sectional study evaluating nurses' pharmacological knowledge revealed that only 72.9% of responses were correct, and 61.5% of nurses cited inadequate knowledge as the primary challenge in drug administration.[1] Similarly, a study in Pune, India, showed that a majority of pediatric nurses possessed only average knowledge of drug calculations, with 61% never having attended relevant workshops.[2]

These knowledge gaps are linked to frequent and sometimes dangerous errors. In a Sudanese pediatric hospital, while many nurses demonstrated good knowledge during drug preparation, their practical application and post-administration protocols were found lacking, highlighting a disconnect between knowledge and practice.[3] Another study concluded that while 85.7% of pediatric nurses knew about drug dosage calculation principles, frequent interruptions and lack of systematic checks contributed to error occurrence.[4]

Despite these challenges, the literature suggests that continuing education and structured intervention programs significantly improve nurses' knowledge and reduce medication errors. For example, a review found that targeted training and the use of advanced technology improved nurses' attitudes and practices in pediatric medication safety.[5] Additionally, nurses' self-efficacy in drug administration has been shown to directly influence error rates, with pediatric nursing competence acting as a mediating factor.[6]

Moreover, practical experience and reflective learning through qualitative studies reinforce the importance of integrating individual responsibility with systemic support. Nurses have cited planning, attention to detail, communication, and adherence to safety checklists as essential to minimizing medication errors in pediatric care.[7]

Given this background, there is a pressing need to assess

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the existing knowledge and practices of nurses in pediatric drug administration, especially in high-risk settings. Such assessments can inform targeted interventions that enhance patient safety and clinical outcomes.

METHODOLOGY

Research Design

This study adopted a descriptive cross-sectional research design aimed at assessing the knowledge and practice of staff nurses regarding pediatric drug administration.

Setting of the Study

The study was conducted in selected SPINH (J.K. Lone hospital) in Jaipur, specifically in pediatric wards where nurses are regularly involved in administering medications to children.

Sample and Sampling Technique

A total of 100 staff nurses were selected using a purposive sampling technique. Inclusion criteria required participants to have a minimum of six months of experience in pediatric care and be willing to participate in the study.

Data Collection Tool

A structured questionnaire was used to collect data. It included three sections:

1. Demographic profile of the participants
2. Multiple-choice questions to assess knowledge of pediatric drug administration
3. A self-reported checklist to assess current practices

Validity and Reliability

The tool's content validity was established through expert review in the fields of pediatric nursing and pharmacology. A pilot study was conducted to test the tool's reliability, which yielded a reliability coefficient of 0.82, indicating high consistency.

Data Analysis

Collected data were analyzed using descriptive statistics such as mean, standard deviation, frequency, and percentage. Analysis was performed using Microsoft Excel and SPSS software to interpret the knowledge and practice levels among nurses.

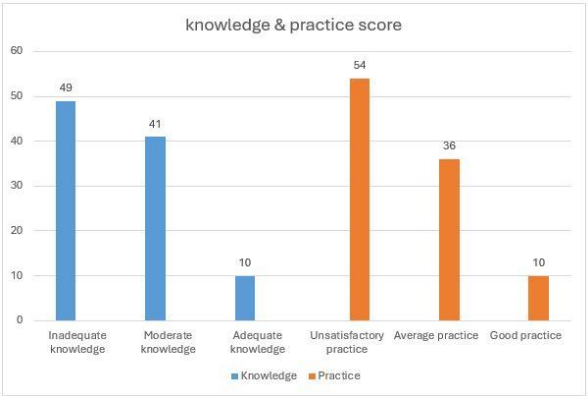

Figure 1: Knowledge and Practice Levels Among Staff Nurses on Pediatric Drug Administration

Above figure 1 bar graph illustrates the distribution of staff nurses (n = 100) based on their levels of knowledge and practice regarding pediatric drug administration. The knowledge levels are categorized as Inadequate (49%), Moderate (41%), and Adequate (10%), while the practice levels are grouped as Unsatisfactory (54%), Average (36%), and Good (10%). The graph reveals that the majority of nurses fall into the moderate knowledge and unsatisfactory practice categories, indicating a gap between understanding and application.

Table 1: Demographic Characteristics of Staff Nurses (n = 100)

Demographic Variable	Frequency (n)	Percentage (%)
Age of Staff Nurses		
≤ 30 years	34	34.0%
31–40 years	28	28.0%
41–50 years	25	25.0%
> 50 years	13	13.0%
Professional Education		
G.N.M	33	33.0%
B.Sc. Nursing / Post Basic B.Sc. Nursing	47	47.0%
M.Sc. Nursing	15	15.0%
Specialized Nursing Course	5	5.0%
Total Years of Experience as Staff Nurse		
< 1 year	29	29.0%
1–5 years	30	30.0%
6–10 years	25	25.0%
> 10 years	25	25.0%
Experience in Pediatric Unit/Ward		
< 1 year	30	30.0%
1–3 years	37	37.0%
4–6 years	23	23.0%
> 6 years	10	10.0%
Currently Working Area		
Pediatric Medical Ward	21	21.0%
Pediatric Surgical Ward	26	26.0%
Pediatric Intensive Care Area	19	19.0%
Other Area	34	34.0%

The table shows that the largest group of participants (34%) were aged ≤ 30 years, and most nurses (47%) had a B.Sc. Nursing or Post Basic qualification. Experience levels were varied, with 30% having 1–5 years of pediatric experience. A considerable number (34%) were working outside core pediatric areas, indicating diverse deployment of nursing personnel. These demographic details help

contextualize the variation in knowledge and practice levels found in the study.

Table 2: Knowledge and Practice Levels of Staff Nurses (n = 100)

Category	Level	Frequency (n)	Percentage (%)
Knowledge Regarding Pediatric Drug Administration			
Inadequate		49	49.0%
Moderate		41	41.0%
Adequate		10	10.0%
Practice Regarding Pediatric Drug Administration			
Unsatisfactory		54	54.0%
Average		36	36.0%
Good		10	10.0%

Table number 2 show that Nearly half of the staff nurses (49%) had inadequate knowledge regarding pediatric drug administration, and only 10% demonstrated adequate knowledge. Similarly, 54% of nurses fell into the unsatisfactory practice category, reflecting unsafe or suboptimal practices. These results underscore a critical gap between knowledge and safe practice, highlighting the urgent need for ongoing training and competency development programs in pediatric pharmacology and clinical care.

Table 3: Association Between Demographic Variables and Knowledge and Practice Scores (n = 100)

Demographic Variable	Knowledge (Chi-Square)	Practice (Chi-Square)	Significance
Age of Staff Nurses	54.287 (Significant) *	43.289 (Significant) *	Significant for both
Professional Education	12.882 (Significant) *	16.288 (Significant) *	Significant for both
Total Experience as Staff Nurse	80.727 (Significant) *	68.413 (Significant) *	Significant for both
Experience in Pediatric Unit/Ward	131.610 (Significant) *	114.943 (Significant) *	Highly significant for both
Currently Working Area	8.545 (Non-significant)	8.109 (Non-significant)	Not significant

*p < 0.05 considered statistically significant.

The association analysis shows that age, professional education, total nursing experience, and experience in pediatric units all had a statistically significant relationship with both knowledge and practice scores ($p < 0.05$). This suggests that more experienced and better-educated nurses tend to have higher competency in pediatric drug administration. However, the current working area did not significantly impact knowledge or practice, indicating that being posted in a pediatric ward alone is not enough—targeted training and experience are key contributors to safe and effective medication administration.

Table 3: Correlation Between Knowledge and Practice Scores of Staff Nurses (n = 100)

Variable	Mean	Median	Standard Deviation (SD)	Correlation (r)	Significance
Knowledge Scores	14.67	17.00	6.08		
Practice Scores	18.85	16.00	6.90	**r = 0.806*** (Positive correlation)	*Significant ($p < 0.05$)*

*** Pearson correlation coefficient (r), *p < 0.05 indicates statistical significance.

DISCUSSION

Medication safety in pediatric settings remains a key priority due to children's increased vulnerability to drug errors, requiring nurses to maintain high levels of knowledge and clinical practice competence. This study assessed the knowledge and practice of staff nurses on pediatric drug administration, as well as their association with demographic variables and interrelation between knowledge and practice scores. The findings provide a critical lens into current competency levels and their influencing factors.

Knowledge of Pediatric Drug Administration

In this study, nearly half of the nurses (49%) demonstrated inadequate knowledge regarding pediatric drug administration, while only 10% were found to have adequate knowledge. The mean knowledge score was 14.67 (SD = 6.08). These results align with several prior studies indicating suboptimal knowledge levels among pediatric nurses. For instance, a cross-sectional study by Lan et al. (2014) found that only 72.9% of pediatric nurses could answer pharmacology questions correctly, with insufficient pharmacological knowledge being a leading cause of medication errors.[29] Similarly, Rai and Devi (2019) reported that 59% of pediatric nurses had only

average knowledge regarding drug calculations, with significant gaps identified in core concept. Rahayu et al. (2020) emphasized that even experienced nurses may struggle with proper medication dosing unless continuously trained and assessed.[8]

Further supporting this, a recent review by Siby et al. (2024) found that consistent educational interventions significantly improved nurses' medication safety practices and knowledge in pediatric hospitals (Siby et al., 2024).

Practice of Pediatric Drug Administration

In this study, more than half of the nurses (54%) demonstrated unsatisfactory practice, with only 10% classified as good. The mean practice score was 18.85 (SD = 6.90), indicating considerable variability. These findings mirror global challenges in translating drug knowledge into safe practice. Alomari et al. (2020) noted a 56.9% reduction in medication errors after targeted nurse-led interventions, suggesting practice quality is highly modifiable with structured support and training.[9]

Gezer & Alemdar (2024) found a clear link between nursing competence and reduction in medication error tendencies, with pediatric nursing skills acting as a key mediator in practice quality. Similar barriers to safe practice—such as workload, distraction, and unclear protocols—were identified by Moraes et al. (2022), suggesting institutional systems also play a crucial role.

Association Between Demographics and Knowledge/Practice

Statistically significant associations were observed between nurses' age, education level, total nursing experience, and their knowledge and practice scores. These findings are consistent with prior studies. For instance, Sears et al. (2016) reported that experienced nurses, though more likely to report errors, committed less severe errors compared to less experienced peers.[10]

Moreover, Mohammed et al. (2022) found that educational programs significantly improve nurses' attitudes and practices regarding pediatric medication errors, especially among those with prior gaps in formal training.[11] These studies emphasize the importance of both academic qualifications and work experience in shaping safe nursing behaviors.

Correlation Between Knowledge and Practice

A strong positive correlation ($r = 0.806$, $p < 0.05$) was observed between knowledge and practice scores, indicating that enhanced knowledge significantly predicts better practice performance. This is reinforced by findings from Can Gezer & Alemdar (2024), who showed that higher drug administration self-efficacy and nursing competency are directly correlated with lower error rates. Similarly, Moraes et al. (2022) and Gimenes et al. (2016) emphasized that structured protocols, when understood and applied, reduce the likelihood of medication-related mishaps.[12]

CONCLUSION

This study highlights significant knowledge and practice gaps among pediatric nurses in drug administration, strongly influenced by demographics and positively correlated with each other. Regular training, clinical exposure, and structured institutional policies are vital for improving pediatric medication safety.

Abbreviations:

Df	Degree of Freedom
N	Number of Sample
SD	Standard Deviation
GOVT.	Government
HI	Research Hypothesis
HO	Null Hypothesis
S**	Sgnificant
NS	Non-Significant
CHI	Chi square value
TAB	Tabulated Value

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Availability of data and materials

Data will be available by emailing at anjukprincess22@gmail.com

Authors' Contributions

Author 1: Conceptualization, Data Collection, Methodology, Writing - Original Draft, Resources, Software, Data Curation, Writing - Review & Editing
Author 2: Approval, Formal analysis, and Supervision.
All authors have read and agreed to the published version of the manuscript. All authors have read the final manuscript.

Ethics approval and consent to participate

This was an observational study, and ethical approval was obtained from the Medical Suerintendent SPINPH J.K. Loan Hospital, Jaipur (Reference No: D.N./3139/14-02-22).

Competing Interest

The authors declare that they have no competing interests.

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ORIGINAL Article

A Comparative Study of Right Shoulder Tip Pain in Low Versus Standard Pressure CO_2 Pneumoperitoneum in Laparoscopic Cholecystectomy

Deepmala Gaur*, Bhanwar Lal Yadav*, Keerti Chaudhary**

ABSTRACT

Background: Gallstones often necessitate cholecystectomy, with laparoscopic cholecystectomy being the gold standard. Pneumoperitoneum (PNP) using carbon dioxide (CO2) can lead to postoperative shoulder pain. This study compares postoperative shoulder pain between low-pressure pneumoperitoneum (LPP) and standard-pressure pneumoperitoneum (SPP) during laparoscopic cholecystectomy.

Materials and Methods: In this prospective interventional study at SMS Hospital, Jaipur, 80 patients undergoing elective laparoscopic cholecystectomy were divided into two groups: LPP (8–10 mm Hg) and SPP (12–14 mm Hg), each with 40 patients. Shoulder pain was assessed using the Verbal Rating Scale (VRS) at 2, 6, 12, 24, and 48 hours postoperatively. Statistical analysis was conducted using the unpaired two-tailed t-test ($P < 0.05$).

Result: Shoulder pain incidence was significantly lower in the LPP group (10%) compared to the SPP group (40%) ($P = 0.00$). Mean VAS scores were consistently lower in the LPP group at all time points, with significant differences noted. At 12 hours, the LPP group had a mean VAS score of 0.62 ± 0.34 compared to 2.92 ± 1.4 in the SPP group ($P = 0.00$). By 48 hours, no LPP patients reported shoulder pain, while the SPP group had a mean VAS score of 0.62 ± 0.21 ($P = 0.00$).

Conclusion: LPP significantly reduces the incidence and severity of postoperative shoulder pain compared to SPP in laparoscopic cholecystectomy, suggesting its potential for improving patient comfort and postoperative outcomes.

Keywords: Gallstones, laparoscopic cholecystectomy, low-pressure pneumoperitoneum, standard-pressure pneumoperitoneum, shoulder pain, postoperative pain.

INTRODUCTION

Gallstones are a common gastrointestinal disorder characterized by hardened bile, often leading to acute or chronic cholecystitis and requiring cholecystectomy. Women are significantly more affected, accounting for 84.9% of cases.1 Cholecystectomy can be performed through open or laparoscopic techniques, with laparoscopic cholecystectomy being the gold standard due to its advantages, such as smaller incisions and quicker recovery. Pneumoperitoneum (PNP) is essential in laparoscopic surgery, utilizing carbon dioxide (CO2) to expand the abdominal cavity. However, residual CO2 can irritate the phrenic nerve, causing postoperative shoulder pain. Although this pain often emerges when patients mobilize post-surgery, its exact mechanism and relationship to residual gas volume remain unclear.2 Despite less postoperative pain compared to open surgery, shoulder pain is a common complication following laparoscopic procedures. Factors such as direct peritoneal irritation from CO2 and diaphragmatic stretching during rapid insufflation contribute to this discomfort. Research on the impact of CO2 insufflation rates on pain is limited. Advancements like single-port laparoscopy have cosmetic benefits, but patients experience similar shoulder pain as with conventional laparoscopy.3,4 This study aims to compare low-pressure versus standard-pressure pneumoperitoneum in reducing the incidence and severity of shoulder pain during laparoscopic cholecystectomy.

METHODS

The study was conducted at the Department of Surgery, SMS Hospital, Jaipur, after obtaining ethics committee approval. It was a prospective interventional study involving patients with cholelithiasis undergoing laparoscopic cholecystectomy, who provided informed consent. The sample size was calculated based on the assumption that 24% of subjects would experience postoperative shoulder pain, requiring 40 patients in each group (total of 80) for 80% power at a two-sided p-value of 0.05. Inclusion criteria included patients over 18 years, undergoing elective surgery for gallstone disease with a normal common bile duct on pre-operative ultrasound. Exclusion criteria encompassed various conditions such as acute inflammation, choledocholithiasis, liver disease, diabetes, significant portal hypertension, suspected gallbladder carcinoma, and any intraoperative or postoperative complications. Postoperative shoulder pain was measured using a verbal rating scale (VRS) at 2, 6, 12, 24, and 48 hours, with pain scores ranging from 1 (no pain) to 10 (unbearable pain). Data collection involved sociodemographic factors and clinical history recorded via

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a pre-designed proforma. Statistical analysis utilized an unpaired two-tailed t-test, with significance set at $P < 0.05$, assessing the frequency and intensity of shoulder pain at specified intervals postoperatively.

RESULTS

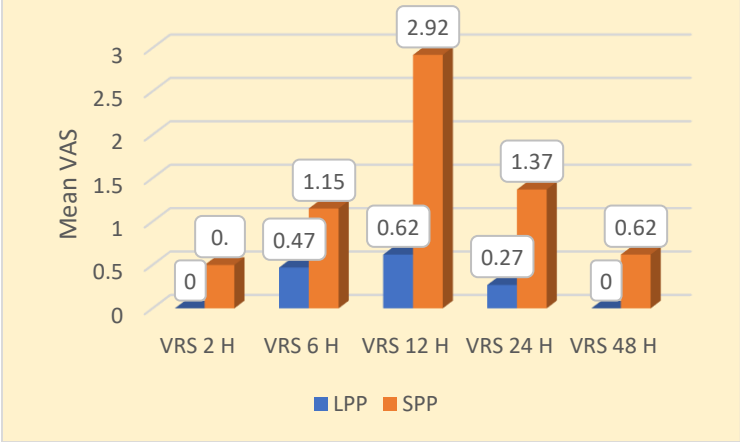
In our study, the LPP group included 11 males (27.5%) and 29 females (72.5%), while the SPP group had 13 males (32.5%) and 27 females (67.5%). Overall, there were 24 male and 56 female patients across both groups, with a P value of 0.20 indicating no statistically significant difference in sex distribution. **Abdallah et al.**[5] reported 9 males (11%) and 71 females (89%) in their study of 80 participants. **Mahajan S et al.**[6] found 15 males and 45 females in the HPP group and 20 males and 40 females in the LPP group. **Ram Chandra et al.**[7] noted a higher prevalence of cholelithiasis among females, with 42% male and 58% female patients in their study of 100 patients. In terms of age distribution, the LPP group had 13 patients (32.5%) and the SPP group had 15 patients (37.5%) in the 18-35 age range, totalling 28 patients (35%). For the 36-50 age group, LPP included 19 patients (47.5%) and SPP had 17 patients (42.5%), totalling 36 patients (45%). In the over 50 age group, both groups had 8 patients each (20%). The P value of 0.13 indicates no statistically significant difference in age distribution between the groups. **Thapa et al.**[8] reported a mean age of 38.20 years in the LPCP group and 37.10 years in the SPCP group. **Ramesh Chandra et al**.[7] found the majority were aged 36–50 years, with mean ages of 39.82 years in the SPP group and 39.86 years in the LPP group. **Abdallah et al.**[5] noted that participants aged 36–50 years underwent LPLC in 65±10.6 minutes on average, while SPLC took 61±9.7 minutes (P>0.05). **Mahajan S et al.**[6] reported a mean age of 40.32 years in the HPP group, slightly higher than the LPP group's 38.32 years.

In our study, 4 patients (10%) in the LPP group reported shoulder pain, while 16 patients (40%) in the SPP group did, totaling 20 patients (25%) across both groups. The significant P value of 0.00 indicates that shoulder pain was significantly more prevalent in the SPP group. Supporting this, **Thapa et al.**[8] found 28% of patients in the LPCP group and 64% in the SPCP group experienced shoulder tip pain. **Abdallah HA et al**.[5] reported shoulder pain in 32.5% of SPLC patients compared to 7.5% in LPLC ($P<0.05$). **Chandra R et al**.[7] noted post-operative shoulder pain in 15 SPP patients and 11 LPP patients. **Anup Shah et al.**[9] also demonstrated significantly lower shoulder tip pain rates after low-pressure LC (11.42%) compared to standard-pressure LC (31.42%) ($p<0.05$). A 2013 meta-analysis by **Hua J et al.**[10] demonstrated that low-pressure pneumoperitoneum in laparoscopic cholecystectomy (LC) resulted in comparable operative times and shorter hospital stays (P=0.01). Our study confirmed significantly lower postoperative shoulder pain in the low-pressure group at all assessed time points, highlighting the effectiveness of this technique in pain management. Our study aligns with findings from **Thapa P et al.**[8] who reported significant VAS score differences between LPCP and SPCP groups at 8 hours (p=0.006) and 12 hours (p=0.008). **Agarwal et al.**[11] noted that 14% of low-pressure patients experienced shoulder tip pain (STP) versus 38% in the standard-pressure group, with significant differences at 6 hours (p=0.002) and 12 hours (p=0.002). **Ali et al**.[12] found lower mean VAS scores in the LPCP group (p=0.001). **Chandra R et al.**[7] similarly observed higher VAS scores in the SPP group, with post-operative shoulder pain in 15 patients from SPP compared to 11 from LPP.

Abdallah et al.[5] confirmed less postoperative shoulder pain in the low-pressure group with statistically significant differences. **Shaha A et al.**[9] showed higher mean intensity of shoulder tip pain after standard-pressure LC at 4, 8, and 24 hours, indicating better pain management with low-pressure pneumoperitoneum. **Agarwal V et al.**[13] also noted greater postoperative shoulder tip pain at these time points after standard-pressure LC compared to low-pressure LC

Tables/ Figures

Fig.1 Comparison of Pain between both groups



CONCLUSION

This study provides compelling evidence that reducing the pressure of pneumoperitoneum to 8 to 10 mm Hg leads to a significant decrease in both the intensity and frequency of postoperative shoulder tip pain. The findings strongly support the widespread adoption of low-pressure pneumoperitoneum in laparoscopic cholecystectomy procedures. By lowering intra-abdominal pressure, surgeons can effectively mitigate the discomfort experienced by patients post-operatively, thereby enhancing overall patient satisfaction and improving recovery outcomes.

Abbreviations

PNP: Pneumoperitoneum
CO_2: carbon dioxide

VRS: verbal rating scale
LPP: low pressure pneumoperitoneum
SPP: standard pressure pneumoperitoneum

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Availability of data and materials
Data will be available by emailing deepmalagaur21nov@gmail.com

Authors' Contributions
- Author1: participated in the investigation, conceptualization, methodology, resources, supervision, validation, writing, reviewing, and editing.
- Author2: participated in the investigation, conceptualization, writing, review, data collection, and editing.
- Author3*: corresponding author participated in data collection, writing, reviewing, and editing.

All authors have read and agreed to the published version of the manuscript. All authors have read the final manuscript.

Ethics approval and consent to participate
The research adhered to the ethical principles outlined in the Declaration of Helsinki (2013). Approval for the study protocol was granted by the SMS medical college and attached hospital Ethics Committee, with a decision number of 785/MC/EC in 2023. Electronic signatures were obtained as informed consent from all individual participants involved in the study. Every procedure conducted during the study complied with the standards of SMS medical college and attached hospital Ethics Committee and aligned with the principles set forth in the 1964 Helsinki Declaration, along with its subsequent amendments.

Competing Interest
The authors declare that they have no competing interests.

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Original Article

A Descriptive study of Adverse Drug Reactions with Causality Assessment and Potential Drug-Drug Interactions in the Outpatients of the Psychiatric Department at SMS Hospital, Jaipur, Rajasthan

Kapil Goyal*, Suchibrata De*

ABSTRACT

Background: Psychotropic drugs can cause a number of Adverse Drug Reactions (ADRs). Polypharmacy is one of the leading causes for ADRs. Clinically significant drug interactions impacting drug response or appearance of serious adverse drug reactions have been documented and can impact long-term outcomes. The objective of this study was to record and analyze the adverse drug reactions (ADRs) due to psychotropic drugs and the potential drug-drug interactions (pDDIs) amongst different psychotropic drugs as well as pDDIs between psychotropic drugs and other co-prescribed drugs.

Methods: This descriptive study was done at the Department of Psychiatry at SMS Hospital, Jaipur, focusing on outpatients attended the Psychiatric OPD for follow up, who were diagnosed to be suffering from any psychiatric illness and prescribed at least one psychotropic drug. A total of 600 prescriptions were analyzed for the ADRs and pDDIs.

Result: Total 40 ADRs were observed in 39 (6.5%) patients. Antipsychotics was the most common group and olanzapine was the most common psychotropic drug suspected of causing ADRs. Tremors was the most common ADR observed. All of the ADRs were non serious and were in a "Recovering" state when the data was collected. Total 1102 pDDIs were observed in all the 600 prescriptions surveyed, out of which 394 prescriptions were showing at least one pDDI.

Conclusion: The overall incidence of ADRs was not very high (6.5%), which reiterates the judicious use of the drugs in the study setting. Majority of prescriptions had only 1-2 pDDIs per prescription.

Keywords: Adverse drug reactions, Drug interactions, Psychotropic drugs, Olanzapine, Causality.

INTRODUCTION

Psychiatry is a branch of medicine that is meant to be deals with mental, emotional or behavioral disorders. Psychiatric disorders constitute a significant problem in the world. Four out of ten health conditions which are known to contribute to the disability adjusted life years, are psychiatric disorders. Research findings shows that in a year, 30% of the global population has a psychiatric disorder.[1] Modern lifestyle and unfulfilled desires lead to diseases like anxiety, depression and schizophrenia, causing exponential rise in the use of psychotropic medication.[2] Psychotropic drugs or psychopharmacological agents are those having primary effects on psyche (mental processes) and are used for treatment of psychiatric disorders.[1] The drug therapy protocol has been changed a lot since the development of newer drugs like Selective Serotonin Reuptake Inhibitors (SSRIs) and Atypical Antipsychotics in the last two decades.[3] Psychotropic drugs can cause a number of Adverse Drug Reactions (ADRs) and some of them can be serious or even fatal. WHO defines an Adverse Drug Reaction as "A response to a drug that is noxious and unintended and occurs at doses, used in human for prophylaxis, diagnosis, or therapy of a disease or for modification of physiological function". Polypharmacy is one of the leading causes for ADRs.[1] Psychotropic polypharmacy can be defined as the concurrent prescription of two or more psychiatric drugs to a patient. It is a major problem in psychiatric practice, which can lead to development of adverse effects in patients.[1] The prevalence of psychotropic polypharmacy is increasing and it is ranging between 13-90%.[4] Psychotropic drugs associated ADRs can, then, cause lack of compliance and at times discontinuation of the treatment. Under-reporting is a problem with ADRs occurring due to psychotropic drugs. Therefore, pharmacovigilance in psychiatry plays a vital role to ensure therapeutic safety by detecting early alarming signals.[1] Pharmacovigilance is the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any drug related problem.[5] Potential DDIs (pDDIs) are those interactions, which can be predicted from the known pharmacological actions of the drugs and have the possibility to alter the effects of the co-administered drug.[8] While life-threatening drug interactions are rare, clinically significant drug interactions impacting drug response or appearance of serious adverse drug reactions have been documented and can impact long-term outcomes. Additionally, the impact of genetic variability on the psychotropic drug's pharmacodynamics

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and/or pharmacokinetics may further complicate drug therapy. Increased awareness of clinically relevant psychotropic drug interactions can aid clinicians to achieve optimal therapeutic outcomes in patients.[7] The need for this study is for observation and analysis of the ADRs occurring due to psychotropic drugs and then assessing all the reported ADRs for Causality using World Health Organization-Uppsala Monitoring Centre (WHO-UMC) scale. Also, studying the potential drug-drug interactions (pDDIs) amongst different psychotropic drugs as well as between psychotropic drugs and other co-prescribed drugs by using Medscape software (online) (http://reference.medscape .com/drug-interactionchecker) will aid clinicians to achieve optimal therapeutic outcomes in patients by increasing awareness of clinically relevant psychotropic drug interactions. It will also help to sensitize the healthcare workers as well as the patients and their attendant for reporting of ADRs occurring due to psychotropic medications.

METHODS

This Descriptive Observational study was carried out in Outdoor patients on psychotropic drugs attending Department of Psychiatry at SMS Hospital, Jaipur after approval from Institutional Ethical Committee (IEC), Research Review Board (RRB) and Department of Psychiatry. Patients of either sex in the age group of 18 years to 60 years attended the Psychiatric OPD for follow up, who were diagnosed to be suffering from any psychiatric illness and prescribed at least one psychotropic drug were included in the study. Patients who were non-co-operative, Patients having mental and behavioral disorders due to psychoactive substance use and Patients who were pregnant/ lactating women were excluded from the study. Those meeting the selection criteria were briefed about the study and written informed consent were obtained from those willing to participate. Their prescriptions were analyzed and the following data was recorded: Number and percentage of different adverse drug reactions (ADRs) observed due to psychotropic drugs, Percentage of adverse drug reactions caused by different groups of psychotropic drugs, Percentage of adverse drug reactions caused by different psychotropic drugs, Numbers of cases in different causality categories (assessed by WHO-UMC scale) and Number of potential drug-drug interactions (pDDIs) observed per patient. The data was collected, compiled in MS-Excel and analyzed for counts and percentages.

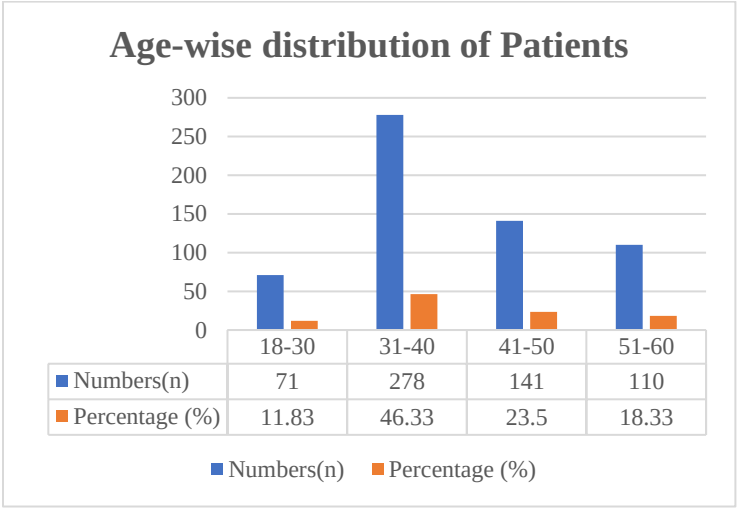
Sample size: Sample size was calculated at 95% confidence level assuming 6.4% incidence of ADRs in patients attending psychiatric department.[1] At the absolute allowable error (precision of 2%) in incidence of ADR, minimum 576 patients attending psychiatric OPD were required as sample size which was further enhance to 600 patients as final sample size expecting 5% non-response attrition.

RESULTS

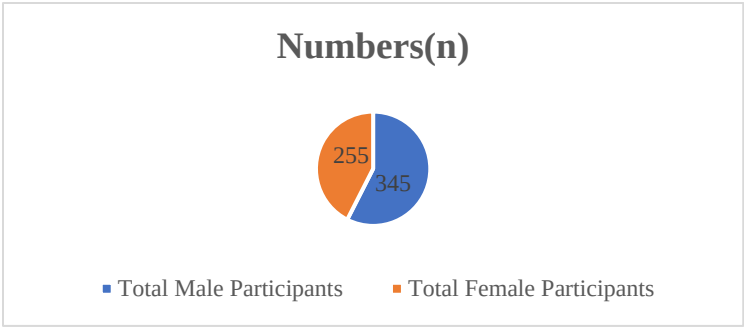
1) Demographic details of study participants

The age group of 31 to 40 years had maximum number of patients [278 (46.33%)] out of the total 600 patients participated. The number of male participants [345/600 (57.5%)] was higher than that of female participants [255/600 (42.5%)].

Graph 1: Age-wise distribution of patients



Graph 2: Numbers of Males and Females participated



2) Pattern of psychiatric disorders

In this study, total 40 ADRs were observed in 39 patients (6.5% of the total participants). Table 1 demonstrates different psychiatric disorders observed in these 39 patients. Thus, Table 1 shows that the most common group of psychiatric disorders observed in the patients having ADRs was “schizophrenia spectrum and other psychotic disorders”.

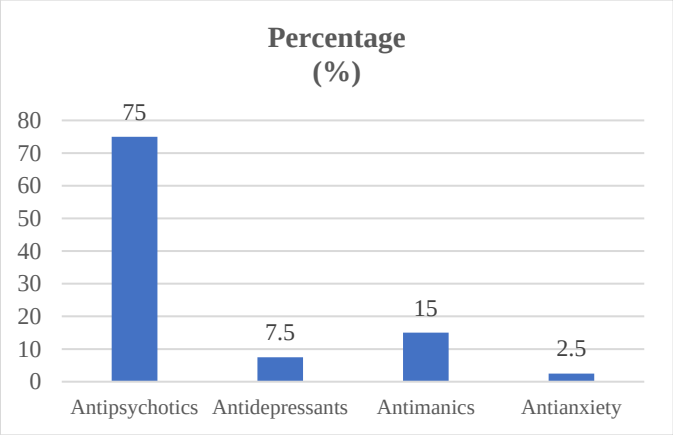
Table 1: Number of Patients suffering from different Psychiatric disorders

Psychiatric disorders as per DSM-5 Classification (American Psychiatric Association, 2013)	Patients in Numbers (n)
Schizophrenia Spectrum and Other Psychotic disorders	25
Bipolar and related disorders	11
Depressive disorders	1
Other psychiatric disorders	2
Total	39

3) Adverse drug reactions due to psychotropic drugs

Graph 3 shows that antipsychotics were the most common drugs causing ADRs (75% of all the ADRs), when compared with all other groups. Graph 4 shows that olanzapine (17 ADRs or 42.50% of total ADRs) was the most common psychotropic drug suspected of causing ADRs. Table 2 shows that "Tremors" was the most common ADR observed due to psychotropic drugs.

Graph 3: Percentage of Adverse Drug Reactions caused by different groups of psychotropic drugs



Graph 4: Percentage of Adverse Drug Reactions caused by different psychotropic drugs

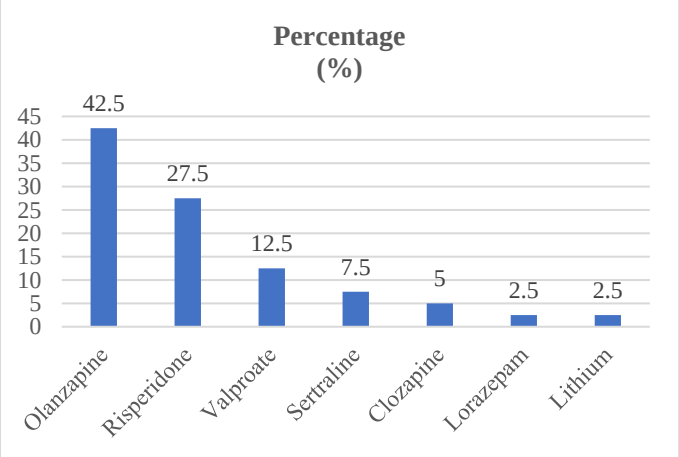


Table 2: Number and Percentage of different adverse drug reactions (ADRs) observed due to psychotropic drugs.

ADR	Number (n)	Percentage (%)
Tremors (EPS)	21	52.50
Dry Mouth	5	12.50
Constipation	4	10
Dizziness	3	7.50
Weight gain	3	7.50
Anorexia	1	2.50
Blurred vision	1	2.50
Nausea	1	2.50
Insomnia	1	2.50
TOTAL	40	100

4) Causality assessment of all the ADRs due to psychotropic drugs using WHO-UMC scale

Out of total 40 ADRs, 38 ADRs were having causality assessment as "possible" and remaining 2 had causality as "probable".

All of the ADRs reported due to psychotropic drugs were "non-serious".

Outcome of ADRs: In all the 39 cases of ADRs, the patients were "recovering" from the ADR when the data was collected.

Management of ADRs: The suspected drug was not withdrawn in any of the patients who developed ADRs. In all the 4 patients who developed constipation as an adverse reaction, all of them were treated for constipation. The dose of the suspected drugs was reduced in following cases as described in Table 3. In remaining 36 cases of ADRs, the dose of the suspected drug was not changed.

Table 3: Adverse drug reactions in which dose was reduced

S.N.	ADR	Suspected Drug	Number of patients
1	Insomnia	Olanzapine	1
2	Blurring of vision	Clozapine	1
3	Anorexia and Nausea	Sertraline	1

5) Potential drug-drug interactions

The pDDIs observed using Medscape software were analysed as given in Table 4 and Table 5.

Table 4: Analysis of potential drug-drug interactions (pDDIs)

Criteria	Result
Total Numbers of pDDIs observed in all 600 prescriptions	1102 pDDIs
Numbers of prescriptions with Zero pDDIs	153 (25.50%) prescriptions
Numbers of prescriptions showing at least One pDDI	394 (65.66%) prescriptions

Table 5: Number of potential drug-drug interactions (pDDIs) observed per patient

Number of pDDIs per patient	Number of Patients
1-2	253
3-5	104
≥ 6	37
TOTAL	394

DISCUSSION

The results obtained from this study demonstrated that the majority of the patients were in their 4th decade of life. Some other similar studies done in India also reported the same finding. The overall incidence of ADRs was not very high (6.5%), which reiterates the judicious use of the drugs in the study setting.

25.50% prescriptions were not having any pDDI. Among the remaining prescriptions, majority of the prescriptions had 1 to 2 pDDIs per prescription, which is not a very high number.

In the present study, maximum number of the patients (278 patients or 46.33% patients) were belonging to the age group of 31 to 40 years. This finding coincides with the study conducted by Thakkar et al. (2013). In the current study, males constituted higher percentage than females. This finding is similar to the study conducted by Mudhaliar et al. (2017).

This study revealed that, among all the psychiatric disorders observed in patients having one or more ADRs, the most common group of psychiatric disorders according to DSM-5 classification was schizophrenia spectrum and other psychotic disorders. The studies conducted by Thakkar et al. (2013) also depicted similar findings.

In this study, out of total 600 patients participated, 39 patients (6.5%) developed at least one ADR due to psychotropic drugs. This finding is similar to the studies done by Hotha et al. (2016), Solanke et al. (2013) and Prajapati et al. (2013), where the incidence of ADRs due to psychotropic drugs was 4.68%, 5.01% and 8.68%, respectively.

Antipsychotics was the commonest group and olanzapine was the most common psychotropic drug suspected of causing ADRs in current study. This finding matched with the study conducted by Gurung et al. (2018). Tremors (extrapyramidal symptoms) was the most common ADR observed due to psychotropic drugs in present study, which is in line with the findings reported by Prajapati et al. (2013) and Gurung et al. (2018).

In this study, among the patients who had ADRs due to psychotropic drugs, the number of patients with causality assessment of ADRs as "possible" was more compared to the number of patients who had causality as "probable". Some other studies like Hotha et al. (2016) and Sridhar et al. (2016) also reported similar findings. None of the ADRs reported due to psychotropic drugs in our study was fulfilling any of the criteria of "seriousness" (Indian Pharmacopoeia Commission, 2014), that's why all the reported ADRs were "non-serious". In contrast to my findings, the study done by Hotha et al. (2016) reported that 73.26% ADRs were non-serious, whereas 26.73% ADRs were considered to be serious.

In this study, for management of ADRs, the suspected drug was not withdrawn in any of the patients who developed ADRs, because the adverse reactions did not significantly disrupt the normal activities of the patients. In contrast to these findings, a study done by Solanke et al. (2013) reported that the suspected drugs had to be withdrawn in cases of some of the ADRs due to psychotropic drugs, while other ADRs subsided on reduction of the dose of the suspected drug.

Total 1102 pDDIs were observed in all the 600 prescriptions surveyed in this study. The study by Deshmukh et al. (2021) revealed that total 1051 pDDIs were identified in 500 outdoor patients. In this study, 65.66% prescriptions showed at least one pDDI and amongst them majority of the prescriptions had 1 to 2 pDDIs per prescription. Range of pDDIs observed per patient was 1 to 13 pDDIs per patient. In the study by Deshmukh et al. (2021) the range was 1 to 21 pDDIs per patient. In patients suffering from psychiatric illnesses, sometimes the principal psychiatric disorder is accompanied by the symptoms of another psychiatric disorder in the same patient. For example, in this study, there were some patients having depressive disorder with anxiety features as the diagnosis. Now such patients have to be treated for depression as well as anxiety, which increases the number of psychotropic drugs prescribed to those patients, which in turn, leads to the rise in the number of pDDIs. Same is the case with the patients with some other diagnoses in my study, like mania with psychotic features, paranoid schizophrenia with depressive features, etc. Therefore, the upper limit of the range of pDDIs observed per patient in my study went up to 13 pDDIs per patient.

CONCLUSION

The ADRs due to psychotropic medications can pose problems to the health of the patients as well as to the compliance of the patients taking those drugs. Psychotropic drugs can interact, either among themselves

or with the other co-prescribed medications, which can lead to complications or failure of treatment. Therefore, it is essential to identify and analyze the ADRs and pDDIs due to psychotropic drugs.

Abbreviations
ADRs: Adverse Drug Reactions
pDDIs: Potential Drug-Drug Interactions
WHO: World Health Organization
UMC: Uppsala Monitoring Centre

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Availability of data and materials
Data will be available by emailing shanu.cool97@gmail.com

Authors' Contributions
- Dr Kapil Goyal*: corresponding author participated in the investigation, conceptualization, methodology, resources, supervision, validation, writing, reviewing, and editing.
- Dr Suchibrata De: participated in the investigation, conceptualization, writing, review, data collection, and editing.

All authors have read and agreed to the published version of the manuscript. All authors have read the final manuscript.

Ethics approval and consent to participate
The research adhered to the ethical principles outlined in the Declaration of Helsinki (2013). Approval for the study protocol was granted by the Office of the Ethics Committee, SMS Medical College & Attached Hospital, Jaipur, with a decision number of 29/MC/EC/2023 in 2024. Signatures were obtained as informed consent from all individual participants involved in the study. Every procedure conducted during the study complied with the standards of Ethics Committee and aligned with the principles set forth in the 1964 Helsinki Declaration, along with its subsequent amendments.

Competing Interest
The authors declare that they have no competing interests.

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Original Article

A Descriptive Study of Prescription Pattern in Pregnant Women attending Antenatal Clinic of Department of Obstetrics and Gynaecology in SMS Hospital, Jaipur, Rajasthan

Suchibrata De*, Kapil Goyal*

ABSTRACT

Background: The Prescription patterns in pregnancy presents a special concern because it is associated with physiological changes in the pharmacokinetic and pharmacodynamic actions of the drugs and also it poses a great risk to the maternal and foetal life. Prescription patterns should be evaluated at certain intervals in order to increase the therapeutic efficacy, decrease adverse effects. The objective of this study was to study Prescription Pattern in Pregnant Women attending Antenatal Clinic of Department of Obstetrics and Gynaecology.

Methods: This Descriptive Observational study was carried out on Pregnant women attending antenatal OPD of Department of Obstetrics and Gynaecology at SMS Hospital, Jaipur. Pregnant women of age 18 years and above with Intrauterine pregnancy were included in the study. A total of 100 prescriptions were analyzed.

Result: In this study, 100 pregnant women attending antenatal outpatient department were interviewed to determine the drug utilization pattern during pregnancy. Iron+Folic Acid, calcium+D3 were the most frequently prescribed drugs. Adherence to the prescribed treatment was assessed using Modified Morisky Scale and maximum pregnant women were aware for the benefits of timely intake of medications and its refill on follow-up.

Conclusion: Evaluation of Drug Utilization Pattern periodically will minimize incidence of risk to foetus and mother during pregnancy.

Keywords: Pregnancy, Drug utilization, Iron, Folic acid, Calcium.

INTRODUCTION

WHO defined Drug Utilization Research in 1977 as "The marketing, distribution, prescription and use of drugs in a society with special emphasis on the resulting medical, social and economic consequences." The principal aim of drug utilization research is to facilitate rational use of drugs in population and so improving the health outcome.[1] The Prescription patterns in pregnancy presents a special concern because it is associated with physiological changes in the pharmacokinetic and pharmacodynamic actions of the drugs and also it poses a studies been raising importance in pharmacoepidemiology along with other areas such as public health, pharmacovigilance, pharmacoeconomics and pharmacogenetics.[1] Nowadays patients are better educated and have larger expectations from health care system and very frequently use several sources of health care. Considering patients need and vast numbers of drugs available, it's very essential to have appropriate prescription. Changes take place in pregnant women's body as well as in the developing foetus in each trimester. Though pregnancy is a physiological condition still this requires additional care and supplementations including folic acid, iron, calcium, vitamins and minerals, which plays pivotal roles in preventing child and maternal morbidity and mortality.[2] About 8% of pregnant women need permanent drug treatment for different chronic diseases and pregnancy induced complications. But unfortunately, due to easy availability of medications coupled with insufficient health services, raised proportions of medicines are used as self-medications, as compared to prescribed medicines which lead to adverse drug reactions and drug interactions during pregnancy.[2] Prescription patterns should be evaluated at certain intervals in order to increase the therapeutic efficacy, decrease adverse effects. Inappropriate prescriptions are be of the fatal problems in developing and transitional countries. Irrational drugs use ultimately lead to reduction in quality of drug treatment, wastage of resources, increased cost of treatment, increased adverse drug reactions and emergence of drug resistance.[3] As per data by All India Origin Chemists and Distributors- Advanced Working, Action and Correction System (AIOCD-AWACS) market research firm, Gynaecology drugs are one of the most selling drugs in pharmaceutical market; they rank as the 8th in all the super groups with 16.4% growth in the month of February 2012. However, they are the least studied drugs in terms of drug utilization studies.[3] Continuous supervision of all medications prescribed among pregnant women is necessary to monitor whether the potential benefits to mother overshadow the threat to the foetus. Additive safety must be taken on the drug use in women who are or may become pregnant specifically all

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the way through her first trimester. Inadequate drug monitoring in pregnant women can lead to consequences such as improper treatment, adverse effects, increased drug burden on pregnant woman. Some drugs are recommended only in certain trimester. This study on prescription pattern among pregnant women will be helpful in understanding the prescription patterns of different drugs in pregnant women in different trimesters and also helps in specific medicines options in pregnancy and also the need to develop and implement systems to prevent exposures to drugs which are known to pose a risk to the mother or foetus.[7]

METHODS

This Descriptive Observational study was carried out on Pregnant women attending antenatal OPD of Department of Obstetrics and Gynaecology at SMS Hospital, Jaipur after approval from Institutional Ethical Committee (IEC), Research Review Board (RRB) and Department of Obstetrics and Gynaecology. Pregnant women of age 18 years and above with Intrauterine pregnancy were included in the study. Pregnant women who were in active labor and with severe eclampsia, severe heart diseases, infectious diseases and any emergency conditions were excluded from the study. Those meeting the selection criteria were briefed about the study and written informed consent were obtained from those willing to participate. Their prescriptions were analyzed and the following data was recorded: Average number of drugs per encounter, Percentage of drugs prescribed by generic name, Percentage of encounters with an antibiotic prescribed, Percentage of encounters with an injection prescribed, Percentage of drugs prescribed from Essential Drugs List (EDL), Rajasthan (Recently updated in 2019), Proportions of cases with Drug Compliance and Proportions of cases with socio-demographic profile (Age, Residency etc.). The data was collected, compiled in MS-Excel and analyzed for counts and percentages.

Sample size: Sample sizes were calculated at 95% confidence level assuming 65.62% of drugs prescribed by generic name among pregnant women in government maternity hospital.[1] At 10% absolute allowable error minimum 87 prescriptions of pregnant woman of a government maternity hospital were required as sample size for the present study which was further enhance to 100 patients as final sample size.

RESULTS

1) DEMOGRAPHIC PROFILE

Tables 1 & 2 shows Demographic Profiles of Pregnant Women.

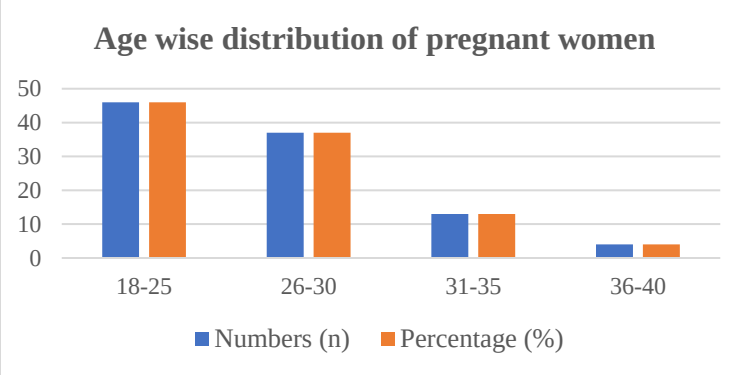
Age wise distribution of pregnant women

It is evident from Table 1 that there are maximum number of pregnant women 46 belonging to age group from 18 to 25 years.

Table 1:

Age Group (in years)	Numbers (n)	Percentage (%)
18-25	46	46
26-30	37	37
31-35	13	13
36-40	4	4
Total	100	100

Graph 1:



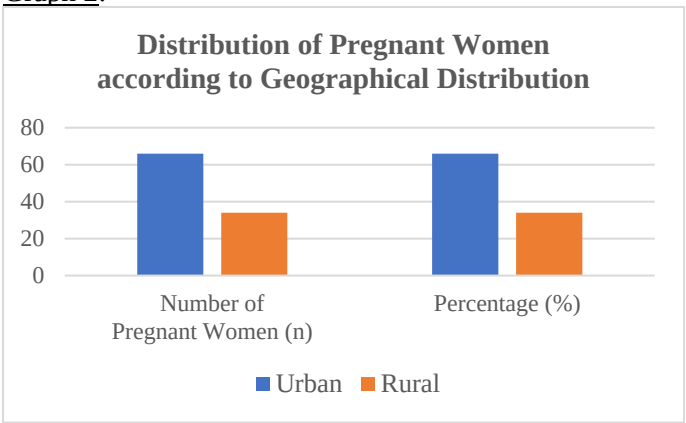
Distribution of Pregnant Women according to Geographical Distribution

Table 2 shows geographical distribution of pregnant women. 66 pregnant women belonged to Urban areas and 34 belonged to Rural areas.

Table 2:

Urban/Rural	No. of Pregnant Women (n)	Percentage (%)
Urban	66	66
Rural	34	34
Total	100	100

Graph 2:



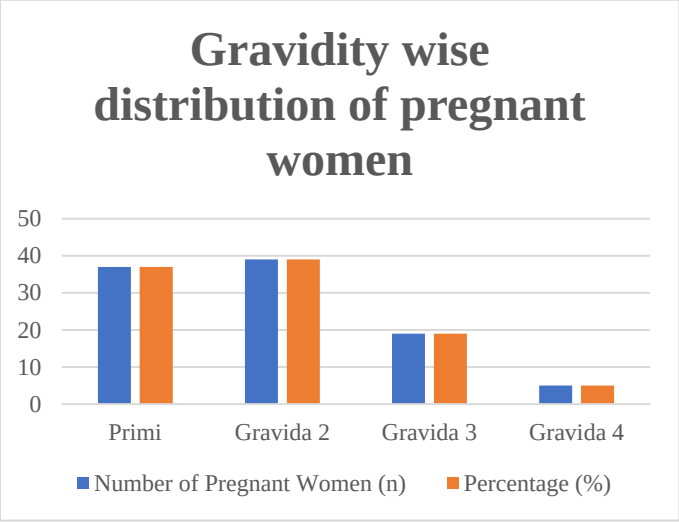
2) GRAVIDITY WISE DISTRIBUTION OF PREGNANT WOMEN

Majority of pregnant women belonged to Gravida 1 and 2.

Table 3:

Gravida	Number of Pregnant Women (n)	Percentage (%)
Primi	37	37
Gravida 2	39	39
Gravida 3	19	19
Gravida 4	5	5
Total	100	100

Graph 3:



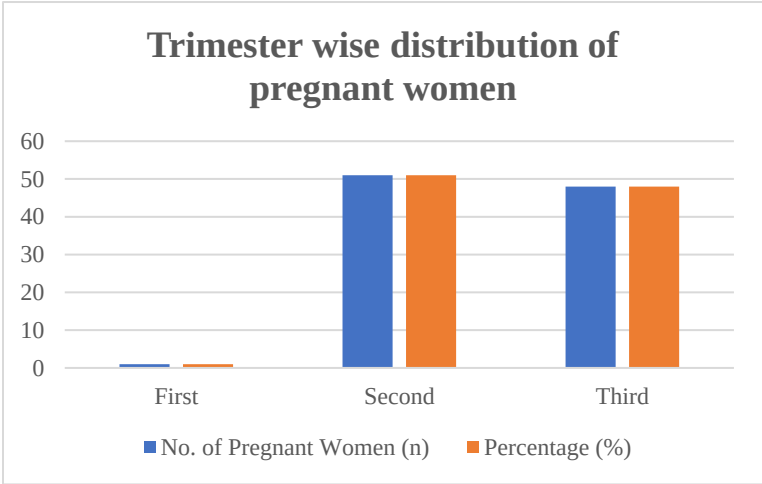
3) TRIMESTER WISE DISTRIBUTION OF PREGNANT WOMEN

In this study among 100 pregnant women, 1 woman participated for the antenatal checkup during the first trimester. 51 (51%) were in second trimester, and 48 (48%) were in third trimester during their visit for antenatal checkups.

Table 4:

Trimester	No. of Pregnant Women (n)	Percentage (%)
First	1	1
Second	51	51
Third	48	48
Total	100	100

Graph 4:



4) DISTRIBUTION OF PRESCRIBED DRUGS

Table 5:

Drug	Dosage Form	Dose	Route	Frequency	Number	Percentage (%)
Progesterone	Tablet	200 mg	Oral	BD	1	1
Albendazole	Tablet	400 mg	Oral	STAT	3	3
Amoxycillin and Potassium Clavulanate	Tablet	500+125 mg	Oral	BD	1	1
Aspirin	Tablet	75 mg	Oral	OD	1	1
Calcium with Vitamin D	Tablet	500 mg+250 IU	Oral	OD	99	99
Cefixime	Tablet	200 mg	Oral	OD	2	2
Clotrimazole	Tablet	500 mg	Vaginal	OD	1	1
Doxylamine & Pyridoxine	Tablet	20+20 mg	Oral	BD	3	3
Ferrous Sulphate with Folic Acid	Tablet	100+0.5 mg	Oral	OD	99	99
Folic Acid	Tablet	5 mg	Oral	OD	1	1
Hyoscine	Tablet	10 mg	Oral	BD	11	11
Labetalol	Tablet	100 mg	Oral	OD	4	4
Metronidazole	Tablet	400 mg	Oral	BD	1	1
Omeprazole	Capsule	20 mg	Oral	OD	2	2
Ondansetron	Tablet	4 mg	Oral	OD	1	1
Pantoprazole and Domperidone	Capsule	40+30 mg	Oral	OD	1	1
Paracetamol	Tablet	500 mg	Oral	BD	2	2
Ranitidine	Tablet	150 mg	Oral	BD	1	1
Mupirocin	Ointment	2%	Topical	BD	1	1
Cough Syrup	Syrup		Oral	1 tsp. SOS	3	3
Thyroxine	Tablet	50 mcg	Oral	OD before breakfast	3	3
TT	Injection	0.5 ml	IM	2 Doses	10	10

5) **DISTRIBUTION OF FIXED DOSE COMBINATION DRUGS PRESCRIBED**

Table 6:

FIXED DOSE COMBINATION DRUGS	Number of times prescribed
Ferrous Sulphate & Folic Acid Tab.	99
Calcium & Vitamin D Tab.	99
Doxylamine & Pyridoxine Tab.	3
Amoxycillin & Clavulanate Tab.	1
Pantoprazole & Domperidone Cap.	1

6) DISTRIBUTION OF ANTIBIOTIC DRUGS PRESCRIBED

Table 7:

ANTIBIOTIC DRUGS	number of times prescribed
Cefixime Tab.	2
Amoxycillin & Clavulanate Tab.	1
Metronidazole Tab.	1
Oint. Mupirocin	1

7) DISTRIBUTION OF INJECTABLES DRUGS PRESCRIBED

In this study, the only injectable prescribed was Tetanus Toxoid (TT) 0.5 ml IM in 2 doses in 10 pregnant women.

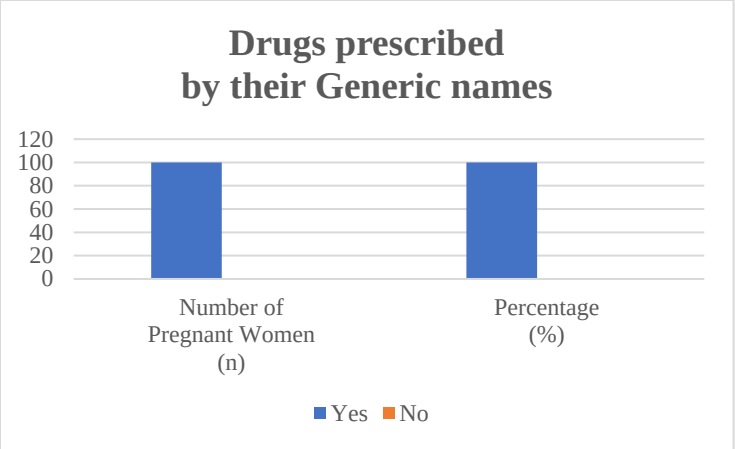
8) DISTRIBUTION OF DRUGS PRESCRIBED BY GENERIC NAME

In this study, drugs by generic name were prescribed in all pregnant women. All the 252 drugs were prescribed by their generic name.

Table 8:

All Drugs prescribed by their Generic names	Number of Pregnant Women (n)	Percentage (%)
Yes	100	100
No	0	0
Total	100	100

Graph 5:



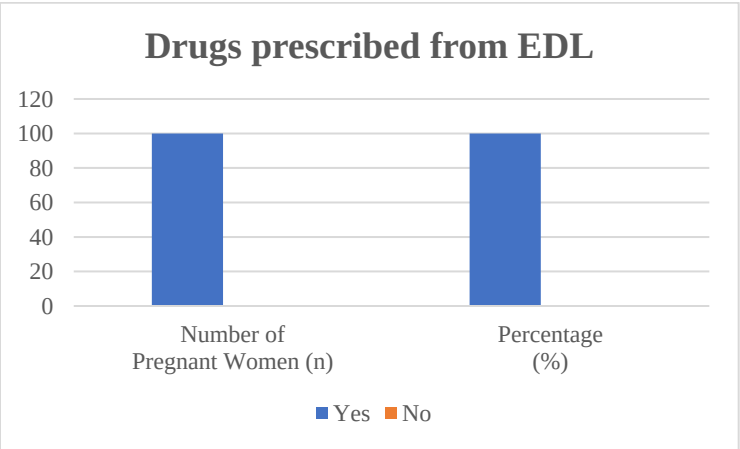
9) DISTRIBUTION OF DRUGS PRESCRIBED FROM ESSENTIAL DRUG LIST (EDL)

Table 9 shows distribution of all drugs prescribed from EDL.

Table 9:

All Drugs prescribed from EDL	Number of Pregnant Women (n)	Percentage (%)
Yes	100	100
No	0	0
Total	100	100

Graph 6:



10) WHO PRESCRIBING INDICATORS

Average number of drugs per encounter

In this study, the number of prescribed drugs ranged from 2 to 6 per pregnant women and total 252 drugs were prescribed to 100 pregnant women. So, average number of drugs per prescription comes 2.52.

Percentage of drugs prescribed by generic name

In this study, drugs by generic name were prescribed in all pregnant women. All the 252 drugs were prescribed by their generic name.

Percentage of encounters with an antibiotic prescribed

In this study, antibiotics were prescribed in 5 (5%) of all pregnant women. Total 5 (1.98%) antibiotics out of 252 drugs were prescribed.

Percentage of encounters with an injection prescribed

In this study, injectables were prescribed in 10 (10%) of all pregnant women. Total 10 (3.97%) out of 252 drugs were prescribed.

Percentage of drugs prescribed from Essential Drugs List (EDL) Rajasthan 2019

In this study, All the pregnant women were prescribed from EDL.

Table 10:

Prescribing Indicators	Results
Average number of drugs per encounter	2.52
Percentage of drugs prescribed by generic name	100%
Percentage of encounters with an antibiotic prescribed	5%
Percentage of encounters with an injection prescribed	10%
Percentage of drugs prescribed from Essential Drugs List (EDL) Rajasthan 2019	100%

11) ADHERENCE

Table 11 shows that 16 pregnant women were low motivated and 13 were having low knowledge on taking their prescribed medication, whereas, 84 were highly motivated and 87 were having high knowledge on taking their prescribed medication.

Table 11:

Modified Morisky Scale (MMS)			
Motivation		Knowledge	
Low (0-1)	16	Low (0-1)	13
High (2-3)	84	High (2-3)	87
Total = 100			

Table 12:

Motivational Scale of Modified Morisky Score (MMS)	Number of Pregnant Women (n)	Percentage (%)
1	16	16
2	53	53
3	31	31
Total	100	100

Graph 7:

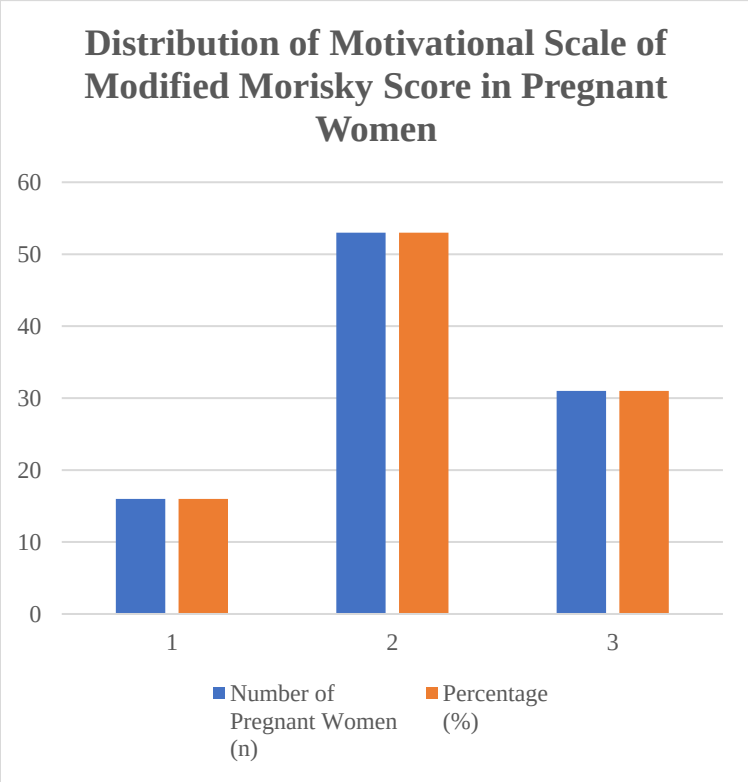
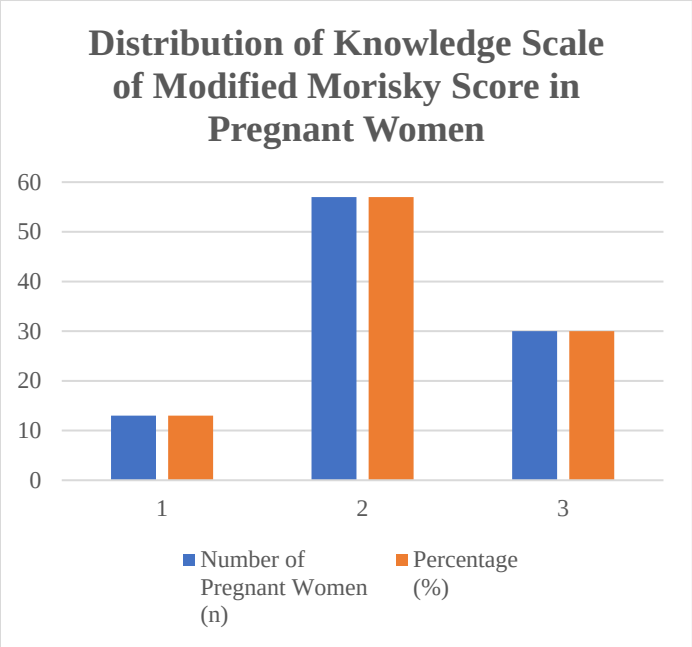


Table 13:

Knowledge Scale of Modified Morisky Score (MMS)	Number of Pregnant Women (n)	Percentage (%)
1	13	13
2	57	57
3	30	30
Total	100	100

Graph 8:



DISCUSSION

In this study out of 100 pregnant women, about 46 were in between 18-25 yrs of age. Age profile of pregnant women differs from country to country. In Indian studies majority of the pregnant women were in between 20-25 yrs whereas in western studies majority of the pregnant women were in between 25-35 yrs of age.

In this study among 100 pregnant women, 1 woman participated for the antenatal checkup during the first trimester. 51 were in second trimester, and 48 were in third trimester during their visit for antenatal checkups. 37 were primigravida, 39 were gravida 2, 19 were gravida 3 and 5 were in gravida 4.

In this study the total numbers of drugs prescribed were 252. The most frequently prescribed drugs were iron+folic acid and calcium+D3 which were prescribed to almost all pregnant women attending antenatal OPD.

Iron+Folic Acids tablets were prescribed as 100+0.5 mg to almost all pregnant women once a day for 1 month until the next antenatal visit. Folic acid tablet was prescribed as 5 mg tablet once a day for 1 month to one pregnant woman until the next antenatal visit. Calcium+D3 was also prescribed to almost all pregnant women as 500 mg of calcium carbonate along with 250 IU of vit. D3 once a day for 1month until the next antenatal visit. Injection T.T was prescribed to 10 pregnant women as 0.5 ml of i.m injection, 2 doses.

In this study almost all women were prescribed drugs only in 2nd and 3rd trimesters. Organogenesis occurs mostly in the 1st trimester. They are exposed to drugs in the phase when organogenesis had already taken place.

In this study, Amoxycillin and Potassium Clavulanate, Metronidazole, Albendazole, Cefixime, Clotrimazole and Mupirocin were prescribed among antimicrobials to 9

Tab. Hyoscine was prescribed among 11 pregnant women. Tab. Progesterone and Tab. Aspirin were prescribed to 1-1 pregnant woman.

Ranitidine was prescribed to 1 pregnant woman as 150 mg tablet twice a day who complained of heart burn. Paracetamol was prescribed to 2 of pregnant women as 500 mg twice a day to those who complained of fever, headache, cold. Thyroxine was prescribed to 3 pregnant women as 50 mcg who had low levels of T3 and T4. They were advised to consume one tablet before breakfast once a day throughout their pregnancies. Labetalol was prescribed as 100 mg tablet once a day to 4 of pregnant women for pregnancy induced hypertension. Amoxycillin and Potassium Clavulanate was prescribed as 500+125 mg tablet, twice a day to 1 of pregnant woman. Clotrimazole was prescribed as 500 mg vaginal tablets once a day to 1 of pregnant woman.

In this study antiemetics were prescribed to 4 of pregnant women as Doxylamine & Pyridoxine tablet 20+20 mg twice a day to 3 pregnant women and Ondansetron tablet 4 mg once a day to 1 of pregnant woman. Among antiulcer drugs, Cap. Omeprazole was the mostly prescribed drug to 2 pregnant women followed by Cap. Pantoprazole+Domperidone and Tab. Ranitidine to 1-1 pregnant woman. In this study, paracetamol was prescribed among analgesics to 2 pregnant women.

In this study a total of 252 drugs with an average of 2.52 drugs/woman were prescribed during antenatal checkups. In this study WHO core drug prescribing indicators did not meet WHO standards. Average number of drugs per prescription was 2.52 that was above the range of the standard set by WHO (1.6-1.8). In this study percentage of drugs prescribed from essential drug list was 100%. Most of pregnant women included in this study are aware of the harmful effect of drugs if being used pregnancy.

Adherence to the prescribed treatment was assessed using MMS. There were two kinds of scores used, motivational and knowledge. 16 pregnant women were low motivated and 13 were having low knowledge on taking their prescribed medication, whereas, 84 were highly motivated and 87 were having high knowledge on taking their prescribed medication. It means that maximum pregnant women were aware for the benefits of timely intake of medications and its refill on follow-up.

CONCLUSION

The total numbers of drugs prescribed were 252. In this study it was observed that the most frequently prescribed drugs were iron+folic acid & calcium+D3 which were prescribed to almost all pregnant women attending antenatal OPD. Ranitidine was prescribed to 1 pregnant woman as 150 mg tablet twice a day. Paracetamol tablet 500 mg was prescribed to 2 of pregnant women. Thyroxine was prescribed to 3 pregnant women who were diagnosed with hypothyroidism. Labetalol was prescribed to 4 of pregnant women who were diagnosed with Pregnancy Induced Hypertension. Amoxycillin and Clavulanate was prescribed to 1 of pregnant woman. Clotrimazole was prescribed to 1 of pregnant woman. It was observed that average number of drugs per prescription was 2.52, percentage of drugs prescribed by generic name was 100%, percentage of encounters with antibiotic prescribed was 1.98%, percentage of encounters with an injection prescribed was 3.97%, and percentage of drugs prescribed from essential drug list was 100%. All drugs prescribed are provided free of cost from the hospital pharmacy. None of the pregnant women was taking any herbal medicine. Most of pregnant women included in this study are aware of the harmful effect of drugs if being used pregnancy. Almost all women had ANC in their 2nd and 3rd trimester in this study except 1 woman who visited in her 1st trimester. There should be awareness among pregnant women regarding the importance of antenatal check-ups in the first trimester and a need of regular antenatal check-ups throughout the pregnancy. On the basis of the finding of this study, 100% of drugs were prescribed from essential drugs list and generic drug prescription was also 100%, according to WHO core prescribing indicators which improve the economic burden in the developing country like India and can improve health status and secure development gains. It was observed that average number of drugs per prescription was 2.52 which is higher than the WHO standard (1.6-1.8) that indicates polypharmacy which may be acceptable in this study as nutraceuticals are mostly prescribed due to deficiency and are safe to use in pregnancy. This can be supported with the other observation of lesser percentage of encounters with antibiotic and injections (1.98% and 3.97%) respectively. Less antibiotic usage may minimize drug resistance and less injectables prescribed in this study denotes less chance of acquiring infections in pregnant women. In spite of illiteracy being common in developing country like India, it was observed that there is good awareness of harmful effects of self-medication and herbal medication among pregnant women. There is a need to increase the awareness about the antenatal care and antenatal visits during the entire period of pregnancy. The pregnant women should be encouraged to take the prescribed drugs at proper time and nutritive food for the good outcome of the pregnancy. Further studies should be done in health centres and health posts to see the extent of prescription during pregnancy.

Abbreviations

ANC: Ante-Natal Care
MMS: Modified Morisky Score
WHO: World Health Organization

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Availability of data and materials

Data will be available by emailing deysuchibrata@gmail.com

Authors' Contributions

- Dr Suchibrata De*: corresponding author participated in the investigation, conceptualization, methodology, resources, supervision, validation, writing, reviewing, and editing.
- Dr Kapil Goyal: participated in the investigation, conceptualization, writing, review, data collection, and editing.

All authors have read and agreed to the published version of the manuscript. All authors have read the final manuscript.

Ethics approval and consent to participate

The research adhered to the ethical principles outlined in the Declaration of Helsinki (2013). Approval for the study protocol was granted by the Office of the Ethics Committee, SMS Medical College & Attached Hospital, Jaipur, with a decision number of 30/MC/EC/2023 in 2024. Signatures were obtained as informed consent from all individual participants involved in the study. Every procedure conducted during the study complied with the standards of Ethics Committee and aligned with the principles set forth in the 1964 Helsinki Declaration, along with its subsequent amendments.

Competing Interest

The authors declare that they have no competing interests.

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Original Article

A Descriptive Observational Study on the Evaluation of Antihypertensive Medications as Fall Risk Increasing Drugs in Elderly Patients Presenting with Injurious Falls at a Tertiary Care Teaching Hospital

Sushil Sharma*, Charu Jain, Monica Jain*, Munesh Kumar*, Jyotsna Bhargava*, Uma Advani***

ABSTRACT

Background: Falls in the elderly are a leading cause of injury, disability, and mortality. Medications, particularly Fall Risk Increasing Drugs (FRIDs), significantly contribute to fall risks in them. Specific medications, such as psychotropics and antihypertensives, heighten fall risks through side effects like dizziness, drowsiness, and orthostatic hypotension.

Aim & Objectives: The evaluation of antihypertensive medications as Fall Risk Medication (FRID) in elderly patients presenting with Injurious Falls.

Material and Methods: A descriptive study was conducted at the Trauma Centre, SMS Hospital, for one year following approval from the Institutional Ethics Committee. Elderly patients (aged ≥65 years) admitted with fall-related injuries were included in the study. Clinical data regarding details of fall-risk-increasing drugs (FRIDs), existing comorbidities, cognitive status, and characteristics of fall-related injuries were gathered.

Results: The mean age was 74.9±7.0 years, with 74.1% females. The probable causes of fall were hypotension (45.5%), diminished vision (37.5%), cognitive impairment (17.0%), and sedation (11.6%). Among FRIDs, Antihypertensives (28.6% calcium channel blockers, 15.2% ACE inhibitors, 8.0% diuretics, and beta-blockers) were the most frequently used medications. The majority of falls were reported during the first few months after the initiation of the antihypertensive therapy. Co-morbidities were hypertension (35.7%), CAD (14.3%), and DM (9.8%).

Conclusion: To mitigate the risk of falls among the elderly, clinicians should exercise caution when starting antihypertensives and implement comprehensive fall prevention strategies, including medication reviews and lifestyle interventions.

Keywords: Elderly, falls, Antihypertensive drugs, Fall Risk Increasing Drugs, fractures, injury prevention.

INTRODUCTION

Annually, 28–35% of those aged 65 and above aged 0-65 and above experience falls, rising to 32–42% for individuals over 70. Additionally, 20–39% develop a fear of falling, leading to reduced activity regardless of injury.[1] Risk factors include a history of falls, use of assistive devices, environmental hazards, muscle weakness, sensory impairments, orthostatic hypotension, diabetes, and osteoporosis. FRIDs include psychotropic drugs (opioids, anxiolytics, hypnotics), cardiovascular drugs (beta-blockers, diuretics), and others classified under WHO's ATC system (Annexure 1). Polypharmacy, commonly defined as using ≥5 medications, further elevates fall risks. The interplay of multiple risk factors compounds the likelihood of falls, increasing from 8% in those with no risk factors to 78% in those with four or more.

As of the latest data, the prevalence of hypertension among adults aged 60 years and older has increased. According to the U.S. National Health and Nutrition Examination Survey (NHANES) for August 2021–August 2023, 71.6% of adults aged 60 and older have hypertension. This upward trend underscores the growing importance of hypertension awareness, early detection, and effective management, especially among older adults.[2] Hypertension, antihypertensive drugs, and fall injury form a complicated triad that may act to exacerbate fall risk in the elderly. Orthostatic hypotension with uncontrolled hypertension is a risk factor for falls. Initiating antihypertensive drugs in hypertensive elderly persons can potentially cause orthostatic hypotension with associated symptoms such as dizziness, fainting, or syncope. This acute effect occurs relatively quickly and may lead to falls. Adjusting these medications may reduce syncope and fall incidences [3] Guidelines such as the Beers Criteria, STOPP/START criteria, and Sweden's Fall Risk Increasing Drugs (FRIDs) classification emphasize identifying inappropriate medications. Despite awareness, FRID prescriptions remain widespread.[4] Under this background, this descriptive observational study was conducted with the following aims and objectives.

1. The evaluation of antihypertensive medications as Fall Risk Increasing Drugs (FRID) in elderly patients presenting

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with Injurious Falls at the trauma centre of a Tertiary Care Teaching Hospital.

2. To describe probable risk factors of falls, the clinical and demographic profile among the elderly patients presenting with Injurious Falls.

MATERIAL AND METHODS

This observational, hospital-based descriptive study was conducted in the Department of Pharmacology and at the Trauma Centre, SMS Medical College, Jaipur, after due permission from the institutional ethical committee for a one-year duration.

Sample size calculation: 112 elderly patients presented with injurious fall, calculated at 95% confidence and 4% absolute error, ensuring sufficient power to verify a minimum 4.7% use of antihypertensive drugs at the time of fall.[5]

Inclusion and Exclusion Criteria

- **Inclusion:** Patients aged ≥65 years admitted with injurious falls at the trauma centre of SMS Hospital and willing to give informed consent for the study
- **Exclusion:** Patients admitted for reasons other than falls (e.g., road traffic accidents)

Data was gathered from medical records and patient or attendant interviews

Outcome Variables

Medication Profile at Time of Fall

Classification of patients' regular medications (defined as drugs taken for at least 30 consecutive days) consumed at the time of admission due to the fall.

Evaluation of antihypertensive medications as Fall-Risk-Increasing Drugs (FRIDs), including: Type of antihypertensive agents used, dosage levels administered, duration of antihypertensive therapy, and proportion of patients on antihypertensive medications.

Comorbidities- Assessment of existing chronic conditions or diseases present in patients at the time of the fall.

Injury Characteristics- Detailed documentation of injury types sustained due to the fall, such as fractures, head injuries, or soft tissue damage.

Probable Cause of Fall- Analysis of potential factors contributing to the fall, including physiological factors or medication side effects.

Cognitive Function Assessment- Evaluation of cognitive status among patients who experienced falls, which can be an independent risk factor for falls. Mini-Mental State Examination (MMSE) was used to assess Cognitive function. The MMSE evaluates cognitive functions across five domains, with scores ≤23 indicating cognitive impairment

Statistical Analysis Statistical analysis involved presenting qualitative data as percentages and proportions, visualized through tables and graphs, and analyzing it using appropriate tests. Quantitative data were expressed as mean ± standard deviation and analyzed with suitable statistical methods, with a p-value <0.05 considered statistically significant.

RESULTS AND OBSERVATIONS

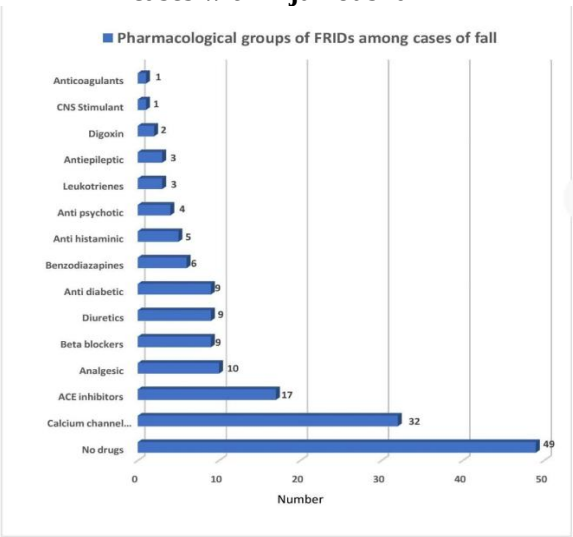
Participants' ages ranged from 65 to over 90 years, with the mean age being 74.9±7.0 years. The majority were in the 70-74 (27.7%) and 75-79 (26.8%) age groups. The data reveals a higher proportion of females (74.1%) compared to males (25.9%), indicating the female population is more prone to fractures post-menopause. Among the injuries reported, the majority were femur fractures, accounting for 76.8% (86) of cases. Others were head injury (5.4%), humerus fractures (6.3%), tibia fractures (6.3%), and fractures of the radius, ulna, and foot, each comprising 4.5%.

Table 1- Probable cause of fall

Probable cause of fall	Number	Percentage
Hypotension	51	45.5
Diminished Vision	42	37.5
Cognitive function impairment	19	17.0
Sedation	13	11.6
Hypoglycaemia	11	9.8
Anaemia	2	1.8
Seizure	1	0.9
Not clear	34	30.4

As per the patient and their attendant's interview and clinical examination at the time of fall, the study reports that the probable causes of falls were hypotension, accounting for 45.5% of cases, followed by diminished vision at 37.5%. Cognitive function impairment in 17.0% (MMSE score<23) and sedation in 11.6% are shown in Table 1. Most patients had normal hearing (73.2%) and vision (59.8%), though a significant number had diminished vision (34.8%) and hearing (26.8%).

Figure 1- Pharmacological group of FRIDs among cases with injurious fall

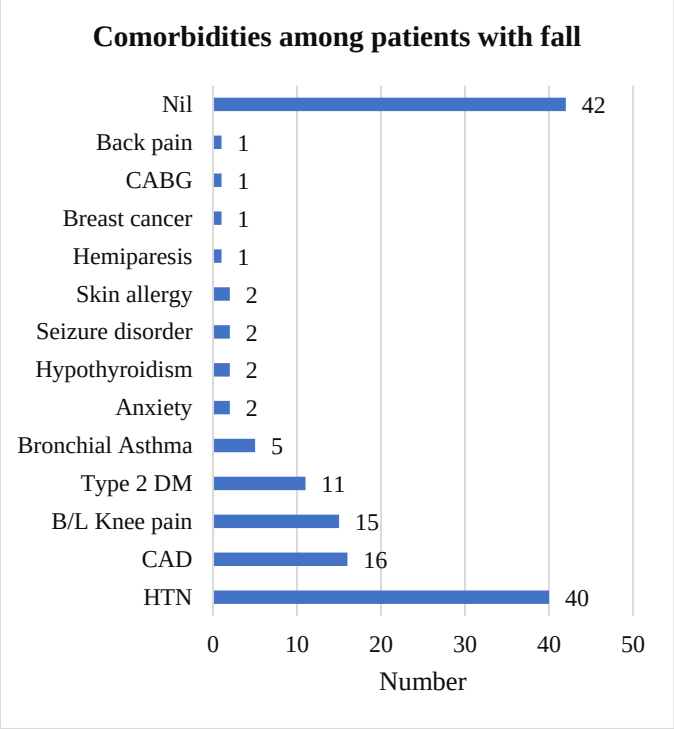


The most commonly consumed drug group was Anti-hypertensive.

Among Anti-hypertensives Calcium channel blockers were the Most Consumed

The elderly patients with injurious falls, 7.1%, were on polypharmacy (≥5 medications). Notably, 28.6% were prescribed at least one fall-risk-increasing drug (FRID), with antihypertensives being the most common (67%), followed by analgesics and benzodiazepines shown in Figure 1. Among antihypertensives, calcium channel blockers (28.6%), ACE inhibitors (15.2%), diuretics (8.0%), and beta-blockers (8.0%) were the most frequently used medications. Importantly, most femur fractures occurred within the first few months of initiating antihypertensive therapy.

Figure 2 – Comorbidities among patients with falls



In the study cohort, hypertension was the most prevalent comorbidity (n=40), followed by coronary artery disease (n=16), bilateral knee pain (n=15), and type 2 diabetes mellitus (n=11). Additional comorbidities included bronchial asthma, anxiety, hypothyroidism, seizure disorders, and skin allergies, as depicted in Figure 2.

DISCUSSION

Falls among older adults are a significant public health concern, with global incidence rates ranging from 224 to 809 per 1,000 person-years. In our study, we observed a higher prevalence of falls among females (74.1%) compared to males (25.9%), aligning with previous research. Srivastava et al identified gender differences in fall-related injuries, with 2.8% of men and 4.3% of women affected.[6] A similar study by Milos et al found that 76% of the participants were female. The results indicate that women are more susceptible to fall-related injuries.[7]

Key intrinsic factors contributing to falls included hypotension (45.5%), visual impairment (37.5%), cognitive deficits (17.0%), sedation (11.6%), and hypoglycaemia (9.8%). These findings are consistent with existing literature that identifies such physiological impairments as significant risk factors for falls in the elderly population. Sharif S I et al. found that most falls were related to underlying illnesses (75%), with dizziness or balance issues (38.8%) and environmental factors like loose carpets (28.2%) contributing to falls [8]

Polypharmacy was present in 7.1% of participants, with 28.6% taking at least one fall-risk-increasing drug (FRID). Antihypertensives were the most commonly prescribed FRIDs (67%), particularly calcium channel blockers (28.6%) and ACE inhibitors (15.2%). Notably, we found that a majority of femur fractures occurred within the first few months of initiating antihypertensive therapy, suggesting a temporal association between the commencement of such medications and increased fall risk. The study done by Debra et al. on hypertensive elderly persons found that an antihypertensive drug had a 43% increased risk of having a hip fracture during the first 45 days following treatment initiation relative to the control periods (incidence rate ratio,1.43; 95% CI,1.19-1.72).[4,9]

The most frequent injury observed was femur fracture (76.8%), followed by head injuries (5.4%) and fractures of the humerus and tibia (6.3% each). Morin L et al. found hip and thigh injuries most common, while Beunza-Sola M et al. reported hip fractures in 63% of fallers. These injury patterns highlight the severe consequences of falls in the elderly and the importance of preventive strategies.[10]

Comorbid conditions such as hypertension (35.7%) and coronary artery disease (14.3%) were prevalent among participants, further elevating the risk of falls. Sharif S I et al. found chronic respiratory disorders (66.7%) and hypertension (55.3%) common among fallers, with 28.6% reporting no comorbidities. Sharma P K et al found that 56.3% of fallers had hypertension, 18.3% had diabetes, and 12.7% had a history of stroke. These findings underscore the necessity of implementing comprehensive care plans that address chronic conditions to reduce fall risk.[11]

The study emphasizes the multifactorial nature of falls in older adults, involving physiological impairments, medication use, and comorbidities. Implementing multifaceted interventions, including medication reviews, management of chronic conditions, and environmental modifications, is crucial to reduce fall incidence and improve outcomes in this vulnerable population.[12]

CONCLUSION

The study concluded that 28.6% of the elderly patients were receiving at least one fall-risk-increasing drug (FRID) at the time of fall, with antihypertensives being the most common (67%), followed by analgesics and benzodiazepines. Among antihypertensives, calcium channel blockers (28.6%), ACE inhibitors (15.2%),

diuretics (8.0%), and beta-blockers (8.0%) were the most frequently used medications. Importantly, most femur fractures occurred within the first few months of initiating antihypertensive therapy. To mitigate the risk of falls among the elderly, clinicians should exercise caution when starting antihypertensives and implement comprehensive fall prevention strategies, including medication reviews and lifestyle interventions.

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Availability of data and materials
Data will be available by emailing jaincharujaincharu2007@gmail.com

Authors' Contributions
Author 1: participated in the investigation, data collection, conceptualization, methodology, resources, writing, reviewing, and editing.
Author2*: corresponding author, participated in the investigation, conceptualization, supervision, validation, writing, review, and editing.
Author 3: participated in writing, reviewing, editing, supervision, and validation**.**
All authors have read and agreed to the published version of the manuscript. All authors have read the final manuscript.

Ethics approval and consent to participate
The research adhered to the ethical principles outlined in the Declaration of Helsinki (2013). Approval for the study protocol was granted by the Institutional Ethics Committee, with a decision number of 354/MC/EC/2023 on 12/04/2023. Electronic signatures were obtained as informed consent from all individual participants involved in the study. Every procedure conducted during the study complied with the standards of the Institutional Ethics Committee and aligned with the principles set forth in the 1964 Helsinki Declaration, along with its subsequent amendments.

Competing Interest
The authors declare that they have no competing interests.

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Annexure 1

Fall risk-increasing drugs (FRIDs) according to the list from the Swedish National Board of Health and Welfare (NBHW)

ATC* code	Drugs/group of drugs
Increase the fall risk	
NO2A	Opioids
N05A (NO5AN excluded)	Antipsychotics (lithium excluded)
N05B	Anxiolytics
N05C	Hypnotics and sedatives
N06A	Antidepressants
May cause or worsen orthostatism	
C01D	Vasodilators used in cardiac diseases
C02	Antihypertensives
C03	Diuretics
C07	Beta blocking agents
C08	Calcium channel blockers
C09	Renin-angiotensin system inhibitors
G04CA	Alpha-adrenoreceptor antagonists
N04B	Dopaminergic agents
N05A (NO5AN excluded)	Antipsychotics (lithium excluded)
N06A	Antidepressants

*Anatomical Therapeutic Chemical classification system.

Annexure 2

Mini-Mental State Examination (MMSE)

Patient's Name Date

Instructions: Ask the questions in the order listed.

Score one point for each correct response within each question and activity

Maximum Score	Patient's Score	Questions
5		What is the year? Season? Date? Day of the week? Month?
5		Where are we now: State? County? Town /city? Hospital? Floor?
3		The examiner names three unrelated objects clearly and slowly, then asks the patient to name all three of them. The patient's response is used for scoring. The examiner repeats them until the patient learns all of them, if possible. Number of trials: ----------
5		"I would like you to count backward from 100 by sevens." [93,86,79,72, 65, ...] stop after five answers. Alternative: "spell WORLD backward." (D-L-R-O-W)
3		"Earlier I told you the names of three things. Can you tell me what those were?"
2		Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.
1		"Repeat the phrase: 'No ifs, ands, or buts."
3		"Take the paper in your right hand, fold it in half, and put it on the floor." (The examiner gives the patient a piece of blank paper.)
1		"Please read this and do what it says." (Written instruction is "close your eye.")
1		"Make up and write a sentence about anything." (This sentence must contain a noun and a verb.)
1		"Please copy this picture." (The examiner gives the patient a blank piece of paper and asks him /her to draw the symbol below. All 10 angles must be present and two must intersect.)
30		Total

Original Article

An Observational Study to Determine the Efficacy of Small Tissue Bite Fascial Closure over Regular Tissue Bite Fascial Closure in Prevention of Surgical Site Infections and Wound Dehiscence in Midline Laparotomies

Priti Padiyar*, Ishan Goyal, Prabha Om*, Rohit Gupta*, Prabhat Bihani***

ABSTRACT

Background: Midline laparotomies are associated with many complications (ileus, intra-abdominal collections, wound infections, wound dehiscence, intestinal obstruction, incisional hernias). Among these, wound related complications (surgical site infection (SSI), wound dehiscence, discharge, incisional hernias) remain the most common, contributing significantly to post operative morbidity/mortality. This study compares two suture patterns (small bites vs. regular bites) for fascial closure in midline abdominal wounds and their effect on postoperative wound site complications.

Methods: 110 patients were selected after assessing inclusion/exclusion criteria and randomly allocated to the small bite and regular bite group, each having 55 participants. All patients underwent midline laparotomies with cases undergoing fascial closure with suture bites taken 0.5–0.8 cm from the wound edge with 0.5 cm spacing, versus a 1 cm distance in the control group. All cases and controls were followed up for one month and assessed for SSI and wound dehiscence.

Results: The study showed statistically significant reduction in the incidence of SSI (p value 0.01, <0.05) and wound dehiscence (p value 0.022, <0.05) in the small bite group, implying superiority of small bite fascial closure over regular bite fascial closure in the prevention of postoperative wound site complications.

Conclusion: The small bite technique for fascial closure in midline laparotomies was associated with significantly lower rates of SSI and wound dehiscence compared to the regular bite technique with results reproducible in the emergency and elective setting. Overall, the small tissue bite closure appears a safer and more effective method in reducing early postoperative wound complications.

Keywords: Small tissue bite fascial closure, SSI, Wound dehiscence.

INTRODUCTION

Laparotomy, also known as celiotomy, is a procedure wherein an incision is made over the abdomen to gain access to the peritoneal cavity. Derived from the Greek words *lapara*, meaning flank, and *tomy* meaning to cut, it essentially translates to a cut over the abdomen used to gain access to the peritoneal cavity. Although laparotomies can be performed by means of various incisions (median, paramedian, oblique, transverse), a standard laparotomy is usually performed via a sagittal, midline incision along the linea alba[1]. Laparotomies can be performed for a variety of conditions, both emergency and elective (intestinal obstruction, perforated GI tract, uncontrollable GI bleeding, blunt/penetrating abdominal trauma, GI tract malignancies). Exploratory laparotomies can be associated with a myriad of complication, including early complications such as paralytic ileus, intra-abdominal collections/abscess, wound infections, abdominal wall dehiscence, pulmonary atelectasis and enterocutaneous fistulae, as well as delayed complications such as adhesive intestinal obstruction and incisional hernias[2]. Among all these, wound related complications remain the most common, and contribute significantly to post operative morbidity and mortality. These complications include surgical site infection (SSI), wound dehiscence, chronic discharge, and delayed complication of incisional hernia.

Surgical site infection is defined as an infection occurring within 30 days of surgery or within 1 year of placement of an implant. Approximately 0.5% to 3% of all surgical patients will develop a surgical site infection[3]. Surgical site infections contribute to 20% of all healthcare-associated infections[4], and patients who develop surgical site infections face higher chances of requiring admission to an intensive care unit (ICU) and are associated with mortality risks ranging from 2 to 11 times greater.

Wound dehiscence is defined as partial or complete postoperative separation of abdominal wound closure. It is the parting of the abdominal musculo-aponeurotic layers of surgical wound. This scenario typically occurs 5 to 8 days following surgery when healing is still in the early stages and the integrity of the wound is entirely dependent on the suture and the suture holding capacity of the tissues.

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Many studies have been conducted to try and understand the implication of suturing techniques on prevention of postoperative wound site complications, including layered vs. single layer closure, interrupted vs. continuous closure, type of suture material, type of knotting, suture length to wound length ratio (SL:WL ratio) and size of stitches.

One such researched technique is the adoption of small bite stitches during fascial closure. Traditionally, large stitches (≥10 mm from the wound edge) were recommended. However, newer studies, considering SL/WL ratio, show that smaller stitches (3–6 mm from the edge) provide stronger wounds, likely due to better alignment and reduced soft tissue inclusion.

Large stitches may include soft tissue such as fat or muscle with low suture holding capacity, increasing the risk of suture cut-through, slackening, and wound complications. Experimental studies support this mechanism and also suggest a higher risk of SSI due to devitalized tissue in large stitches. Contradictory to older beliefs, non-randomised studies show higher wound infection and hernia rates with large stitches. Soft tissue compression and poor perfusion may cause these complications. There's also concern about anterior-posterior separation of aponeurotic edges with large stitches due to soft tissue interposition. This has yet to be investigated in clinical or experimental studies.

METHODS

The study was a prospective, observational study conducted in the General Surgery Department at a tertiary care centre at Jaipur, Rajasthan. The study was carried out between January 2024 and March 2025. All patients undergoing midline laparotomies and fulfilling selection criteria were studied and a total of 110 patients were selected, of which 55 patients underwent small tissue bite fascial closure, and 55 patients underwent regular tissue bite fascial closure. The participants were monitored postoperatively for a period of one month for surgical site infections and wound dehiscence.

Closure in the small bite group was done with Polydioxanone No. 1 reverse cutting suture in a continuous fashion. Suture bites were taken 0.5–0.8 cm from the wound edge with 0.5 cm spacing. SL:WL ratio of 4:1 was ensured. When not feasible with a single suture, the incision was closed from both ends with sutures tied at the midpoint. Similarly, in the regular bite group, midline fascial closure was performed using Polydioxanone No. 1 reverse cutting suture in a continuous manner. Suture bites were taken 1 cm from the wound edge with 1 cm inter-suture spacing and ensuring a SL:WL ratio of 4:1. In both groups a self-locking Aberdeen knot with at least 6 throws was used at the end.

All data was collected using proformas which included demographic details, clinical history and examination, operative details, post-operative outcomes and blood investigations of the patient and was recorded on a Microsoft Excel spreadsheet. Data was analysed using SPSS software (version 26.0).

RESULTS

The study showed a significantly less incidence of SSI and wound dehiscence in the small tissue bite group as compared to the regular tissue bite group (p value<0.05). In the small bite group, 9 out of 55 patients (16.4%) developed SSI, whereas in the regular bite group, the incidence was markedly higher at 21 out of 55 patients (38.2%) with a p value of 0.01 (<0.05). On assessment of wound dehiscence, in the small bite group, only 3 patients (5.5%) experienced wound dehiscence, whereas in the regular bite group, the incidence was significantly higher at 11 patients (20%) with a p value of 0.02 (<0.05).

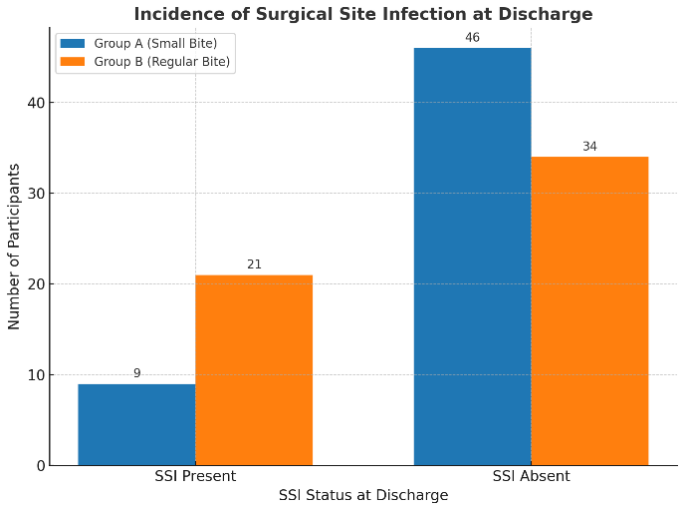
Table 1: Incidence of Surgical Site Infection (SSI)

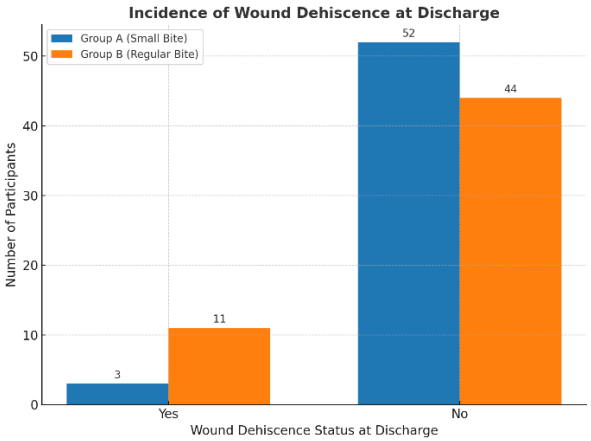
Group	SSI Present	SSI Absent	Total
Small Bite	9	46	55
Regular Bite	21	34	55
Total	**30**	**80**	**110**
Chi-square value (χ^2) = 6.60 **Degrees of freedom (df)** = 1 **p-value** = 0.010			

Table 2: Incidence of Wound Dehiscence

Wound Dehiscence	Group A (Small Bite)	Group B (Regular Bite)	Total
Yes	3	11	14
No	52	44	96
Total	**55**	**55**	**110**
Chi-square value (χ^2) = 5.24 **Degrees of freedom (df)** = 1 **p-value** = 0.022			

Figure 1: Incidence of SSI and Wound Dehiscence





On further analysis of the incidence of SSI and wound dehiscence in both groups, comparing their incidence in the emergency and elective setting, it was found that small bite fascial closure showed a significantly reduced incidence of SSI (p value <0.05) in both, emergency as well as elective setting, whereas, there was a significantly reduced incidence of wound dehiscence only in the emergency setting. There was a reduced incidence of wound dehiscence in the elective setting in the small bite group, however the results were not statistically significant (p value 0.177, >0.05)

Table 3: Incidence of SSI in Emergency and Elective Setting

Group	Emergency Setting			Elective Setting		
	Yes	No	Total	Yes	No	Total
Small Bite	9	32	41	0	14	14
Regular Bite	15	15	30	6	19	25
Total	24	47	71	6	33	39
P value	0.014			0.046		

Figure 2: Incidence of SSI in Emergency and Elective Setting

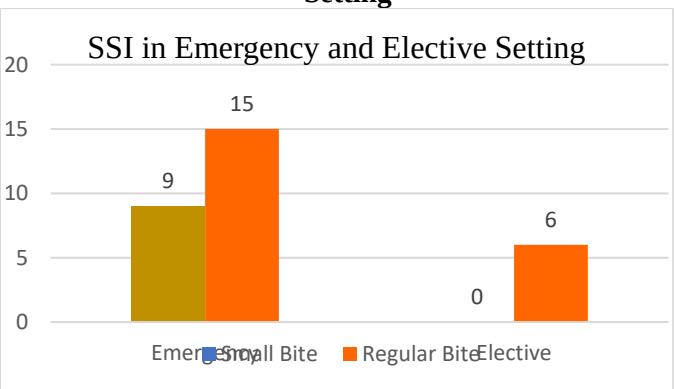
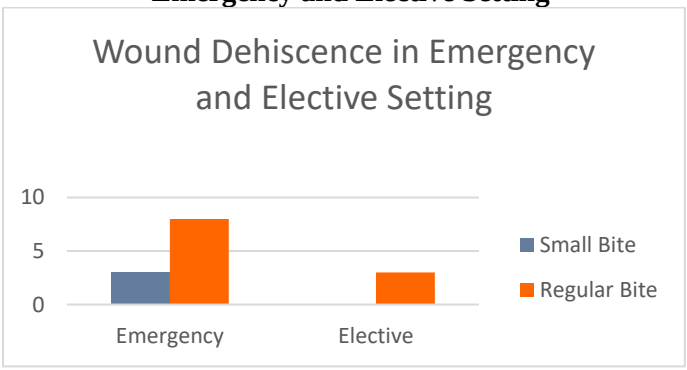


Table 4: Incidence of Wound Dehiscence in Emergency and Elective Setting

Group	Emergency Setting			Elective Setting		
	Yes	No	Total	Yes	No	Total
Small Bite	3	38	41	0	14	14
Regular Bite	8	22	30	3	22	25
Total	11	60	71	3	36	39
P value	0.026			0.177		

Figure 3: Incidence of Wound Dehiscence in Emergency and Elective Setting



There was no significant difference in the age and sex distribution of both groups.

Table 4: Sex Distribution of Study Participants

Sex	Group A (Small Bite)	Group B (Regular Bite)	Total
Male	38	46	84
Female	17	9	26
Total	**55**	**55**	**110**
Chi-square value (χ^2) = 3.22 **Degrees of freedom (df)** = 1 **p-value** = 0.073			

Table 5: Age Distribution of Study Participants

Age Group (Years)	Group A (Small Bite)	Group B (Regular Bite)	Total
18 – 30	18	17	35
31 – 40	7	7	14
41 – 50	15	7	22
51 – 60	8	13	21
> 60	7	11	18
Total	**55**	**55**	**110**
Chi-square value (χ^2) = 5.02 **Degrees of freedom (df)** = 4 **p-value** = 0.286			

There was no significant difference between both groups in duration of surgery (p value 0.114, >0.05) or duration of hospital stay (p value 0.783, >0.05).

An evaluation of confounding variables which contribute independently to wound healing was also carried out and the only variable which offered any significant contribution was jaundice.

Table 6: Distribution of Associated Risk Factors

Risk Factor	Group A	Group B	p-value
Postoperative Distension	17	14	0.525
Intra-peritoneal Sepsis	26	23	0.565
Cough	23	22	0.846
Intra-abdominal Malignancy	7	14	0.089
Malnutrition	5	10	0.380
Anemia	19	17	0.684
Steroid Use	0	1	0.315
Pre-op Hypovolemia	16	8	0.065
Post-op Hypovolemia	4	2	0.401
Hypoxia	11	11	1.000
Uraemia	7	7	1.000
Jaundice	0	7	**0.006**
Sepsis	5	8	0.376
Smoker	20	27	0.177

Figure 4: Small Bite Fascial Closure

DISCUSSION

Surgical site infections remain a significant cause of hospital-acquired morbidity, constituting the third most frequent nosocomial infection. They are responsible for approximately 14–16% of hospital-acquired infections overall and up to 38% of infections in surgical patients. The presence of SSI prolongs hospitalization, increases healthcare expenditure, and leads to substantial psychological, physical, and financial stress for patients. Likewise, wound dehiscence or burst abdomen represents a severe and potentially life-threatening complication following abdominal surgery. Associated with considerable morbidity and mortality, it significantly burdens both patients and the healthcare system. Global prevalence of wound dehiscence is reported to range from 1–3%, whereas in India, rates vary widely, ranging from 0–5% in elective cases and 10–30% in emergency surgeries.

The development of SSI and wound dehiscence is multifactorial. Patient-related risk factors such as advanced age, malnutrition, pre-existing infections, and comorbid illnesses, along with procedure-related variables like the duration of surgery, surgical technique, choice of suture material, and aseptic conditions, play a pivotal role. These complications not only prolong recovery and hospital stay but also diminish the patient's quality of life and productivity.

In the present study, the incidence of surgical site infection (SSI) at discharge was significantly lower in the small bite group (16.4%) compared to the regular bite group (38.2%), with a p-value of 0.010, indicating a statistically significant difference. These findings are in strong concordance with those reported by HS de Vries et al.[5], who found a significantly lower SSI rate of 17% in the small bite group compared to 28% in the large bite group ($p = 0.02$). Similarly, Erwin Yii et al.[6] in a meta-analysis demonstrated a reduced SSI rate with small bites (OR = 0.68, 95% CI [0.51–0.91]). Ana Caroline Dias Rasador et al.[7] also found a lower SSI risk in the small bite group (RR = 0.68, $p = 0.002$). Gunjot Singh Ghai et al.[8] observed a significantly higher incidence of SSI in the regular bite group, as did Jain et al.12 (20 patients in large bite vs. 11 in small bite; $p = 0.014$). Hassan et al.[11] reported a similar pattern with 35.6% SSI in the large bite group and 19.7% in the small bite group ($p = 0.002$). Gandhi et al.[13] found fewer superficial, deep, and organ-space infections in the small bite group (30.7% vs. 57.7%; $p < 0.0255$). D Millbourn et al.[9] also observed fewer infections with small stitches, irrespective of other risk factors. Although R. Sharma et al.[10] did not find a significant difference in SSI rates, they did report reduced suture-related complications with small bites. Collectively, these findings reinforce the conclusion that the small bite fascial closure technique is associated with a significantly lower risk of postoperative SSI.

In the present study, wound dehiscence at discharge was significantly lower in the small bite group, with only 3 patients (5.5%) affected, compared to 11 patients (20%) in the regular bite group ($p = 0.022$), highlighting a statistically significant reduction with the small bite technique. These findings are in line with those of Jain et al.[12], who reported wound dehiscence in 8 patients (20%) with small bites versus 18 (45%) with large bites ($p = 0.016$). Gunjot Singh Ghai et al.[8] also found a lower rate of dehiscence in the small bite group during immediate follow-up. Hassan et al.[11] observed wound dehiscence in 7.38% of patients with small bites versus 15.84% with large bites, though the

difference was not statistically significant, the trend favoured small bites. Gandhi et al.[13] and D Millbourn et al.[9] similarly documented higher rates of wound-related complications in the regular bite group. HS de Vries et al.[5] noted a trend toward fewer incisional hernias (a long-term surrogate of fascial failure) with small bites, indirectly supporting improved fascial integrity. Ana Caroline Dias Rasador et al.[7] emphasized that small bites were associated with better wound stability, and their pooled data showed no increase in dehiscence. Erwin Yii et al.[6] echoed this in their meta-analysis, showing a lower—but statistically borderline—risk of burst abdomen with small bites. R. Sharma et al.[10] and D Millbourn et al.[9] further reinforced that suture technique significantly impacts early fascial breakdown, with small bites outperforming traditional methods. The consistency across these studies strengthens the evidence that small bite fascial closure effectively reduces the risk of early postoperative wound dehiscence.

In the present study, a higher proportion of participants underwent emergency surgeries (64.5%), with 74.5% in the small bite group and 54.5% in the regular bite group. This difference was statistically significant ($p = 0.028$), suggesting a greater number of urgent procedures in the small bite group. Emergency surgeries are often associated with higher risk of SSI and wound complications due to contamination and limited preoperative optimization. However, despite the higher proportion of emergency cases, our study still observed reduced wound complications in the small bite group, highlighting the efficacy of the technique even in high-risk scenarios. This observation is consistent with findings by Hassan et al.[11], who reported a predominance of emergency surgeries (71.9%) and still found significantly lower SSI in the small bite group. Similarly, Gandhi et al.[13] noted that small bite closure was associated with fewer SSIs in emergency laparotomies compared to regular bite closure. Gunjot Singh Ghai et al.[8] also included emergency cases and showed favourable outcomes with the small bite technique. While HS de Vries et al.[5] and D Millbourn et al.[9] did not differentiate between elective and emergency procedures, their findings supported small bites across varied surgical contexts. Jain et al.[12], R. Sharma et al[10], and Ana Caroline Dias Rasador et al.[7] included both types of surgeries but did not find type of surgery to significantly alter the comparative effectiveness of small bite closures. Thus, our study affirms that small bite closure remains advantageous even in emergency settings, consistent with the broader literature.

Abbreviations

SSI: Surgical Site Infection
SL:WL: Suture Length:Wound Length
GI: Gastrointestinal

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Authors' Contributions:
Author1*: participated in the investigation, conceptualization, methodology, resources, supervision, validation, writing, reviewing, and editing.
Author2: corresponding author participated in data collection, writing, reviewing, and editing.
Author3: participated in the investigation, conceptualization, writing, review, data collection, and editing.
Author4: corresponding author participated in data collection, writing, reviewing, and editing.
Author5: corresponding author participated in data collection, writing, reviewing, and editing.
All authors have read and agreed to the published version of the manuscript. All authors have read the final manuscript.

Ethics approval and consent to participate: The research adhered to the ethical principles outlined in the Declaration of Helsinki (2013). Approval for the study protocol was granted by the SMS Medical College Ethics Committee, with a decision number of 416 in 2023. Electronic signatures were obtained as informed consent from all individual participants involved in the study. Every procedure conducted during the study complied with the standards of Institutional Ethics Committee and aligned with the principles set forth in the 1964 Helsinki Declaration, along with its subsequent amendments.
Competing Interest: The authors declare that they have no competing interests.

Original Article

Effectiveness of 3-Day Prophylactic Negative Pressure Wound Therapy versus Conventional Dressing on Closed Abdominal Incisions: An Observational Study

Ishan Goyal*, Prabhat Bihani, Praveen Joshi*, Prabha Om*, Priti Padiyar***

ABSTRACT

Background: Surgical site infections (SSI) and other postoperative wound complications remain significant challenges in abdominal surgeries, especially in resource-limited settings. Negative Pressure Wound Therapy (NPWT) has emerged as a promising prophylactic approach to improve wound healing outcomes.

Methods: A hospital-based, randomized observational study was conducted in the Department of General Surgery, SMS Medical College, Jaipur. Ninety-six patients undergoing midline laparotomy were randomized into two groups: Group A (n=48) received conventional dressing, while Group B (n=48) received NPWT for the first 3 postoperative days. Wound status was assessed clinically on postoperative Day 4 and Day 7 for SSI, seroma, hematoma, dehiscence, and delayed healing. Final healing status and hospital stay duration were also documented.

Results: On Day 4, seroma occurred in 8.3% of Group A and 0% of Group B (p=0.041). By Day 7, SSI was significantly higher in Group A (22.9%) than in Group B (4.2%) (p=0.007). Delayed healing was noted in 12.5% of Group A and none in Group B (p=0.011). Mean hospital stay was significantly reduced in Group B (2.23 ± 0.52 days) compared to Group A (3.79 ± 0.85 days) (p<0.001). Final wound healing was achieved in 95.8% of NPWT patients versus 62.5% in the conventional group (p<0.001).

Conclusion: Short-duration prophylactic NPWT significantly reduces early postoperative complications such as seroma, SSI, and delayed healing, while enhancing overall wound healing and shortening hospital stay. These findings support the use of NPWT as an effective intervention for high-risk abdominal surgeries, particularly in settings with constrained resources.

Keywords: Negative Pressure Wound Therapy, Surgical Site Infection, Laparotomy, Wound Healing, Prophylactic Dressing, Midline Incision.

INTRODUCTION

Surgical site infections (SSIs) remain one of the most common and challenging postoperative complications, contributing substantially to morbidity, mortality, and healthcare expenditure.[1] The Centres for Disease Control and Prevention (CDC) reports that SSIs account for nearly 20% of healthcare-associated infections and occur in 2–5% of patients undergoing inpatient surgical procedures.[2] These infections are associated with prolonged hospitalization, increased readmission and reoperation rates, delayed recovery, and, in severe cases, elevated mortality.[3] The risk is particularly pronounced in abdominal surgeries due to possible contamination from gastrointestinal contents, impaired healing, and exposure to endogenous bacteria.[4]

Closed abdominal incisions, especially those following elective or emergency laparotomies, are vulnerable to SSIs, seroma, hematoma, wound dehiscence, and delayed healing.[5] Such complications not only prolong recovery but also negatively impact quality of life, causing psychological distress, pain, and financial burden.[6] Conventional wound management with gauze dressings provides only passive protection.[7] These dressings are limited in their ability to control exudate, maintain a moist environment, and reduce bacterial load—factors critical for effective wound healing.[8]

Negative Pressure Wound Therapy (NPWT), also termed vacuum-assisted closure (VAC), has emerged as an advanced modality in wound management.[9] It applies controlled sub-atmospheric pressure via a sealed dressing connected to a vacuum device, thereby promoting healing by removing exudates, enhancing local perfusion, stimulating granulation tissue, decreasing bacterial contamination, and maintaining a moist wound environment.[10] NPWT has demonstrated efficacy in accelerating healing and reducing infection rates in open wounds, chronic ulcers, pressure sores, and traumatic injuries.[11]

Recently, interest has grown in the prophylactic application of NPWT on closed surgical incisions.[12] Early evidence suggests potential benefits in reducing postoperative complications, particularly among high-risk patients, although most studies have focused on orthopaedic and cardiovascular procedures, with limited data in abdominal surgery.[13] Exploratory laparotomies, in particular, are associated with a high incidence of wound

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complications due to contamination, increased intra-abdominal pressure, and complex wound closure.[14,15] Conventional dressings offer only a barrier effect[16], whereas NPWT may reduce these risks by maintaining a closed wound environment and preventing fluid accumulation.[17]

The rationale for a 3-day prophylactic NPWT protocol lies in providing protection during the critical early phase of healing while minimizing cost, discomfort, and device-related adverse effects. This study therefore aims to evaluate the effectiveness of 3-day prophylactic NPWT compared with conventional gauze dressings in reducing wound complications following abdominal surgery, thereby addressing a significant evidence gap and contributing to improved postoperative care.

MATERIAL & METHODS

This prospective observational study was conducted in the Department of General Surgery, SMS Medical College and Attached Hospitals, Jaipur, Rajasthan, India, over a period of 12 months from **January 2024 to December 2024**. The study was approved by the Institutional Ethics Committee of SMS Medical College, Jaipur, under IEC number **MC/EC/66/2023, dated 08 January 2024**. The ethical clearance letter and supporting correspondence were documented through official emails. Informed written consent was obtained from all patients prior to enrollment.

The study included patients undergoing elective or emergency midline laparotomy. Patients with pre-existing wound infections, immunocompromised status, gross intraoperative contamination requiring open abdomen, or those unwilling to participate were excluded. Eligible patients were allocated into two groups: one receiving prophylactic Negative Pressure Wound Therapy (NPWT) and the other conventional sterile gauze dressing.

In the NPWT group, a commercially available vacuum-assisted closure device was applied immediately after primary closure of the abdominal incision. Continuous negative pressure of –125 mmHg was maintained, and the dressing was retained for three days before removal. In the control group, standard sterile gauze dressing was applied at the time of wound closure, with routine dressing changes performed subsequently. Both groups received standard perioperative care, including antibiotic prophylaxis, analgesia, and postoperative monitoring in accordance with institutional protocols.

Patients were assessed for demographic details, comorbidities, type of surgery, and intraoperative findings. The primary outcome was the incidence of surgical site infections (SSIs), defined according to the Centres for Disease Control and Prevention (CDC) criteria. Secondary outcomes included seroma, hematoma, wound dehiscence, and duration of postoperative hospital stay. Patients were monitored daily during their hospital stay and followed up until suture removal or complete wound healing, whichever occurred later.

Data were compiled and analyzed using Microsoft Excel and SPSS software version [insert version]. Continuous variables were expressed as mean ± standard deviation and compared using Student's t-test, while categorical variables were expressed as percentages and compared using the chi-square test or Fisher's exact test where appropriate. A *p*-value of <0.05 was considered statistically significant.

RESULTS

The study included 96 patients undergoing midline laparotomy, randomized into two equal groups. Group A received conventional gauze dressing, while Group B received 3-day prophylactic Negative Pressure Wound Therapy (NPWT). Observations were recorded regarding baseline characteristics, wound classification, postoperative complications, hospital stay, and final outcomes.

Table 1. Distribution of Subjects According to Age, Gender, and BMI

Parameter	Group A (Conventional)	Group B (NPWT)	p-value
Age (Mean ± SD, years)	43.00 ± 11.43	41.38 ± 13.64	0.529
Gender (M/F)	32 / 16	32 / 16	1.000
BMI (Mean ± SD, kg/m²)	27.14 ± 0.85	25.38 ± 0.52	0.542

The two groups were statistically comparable in terms of age, gender, and BMI. The mean age was slightly higher in Group A, but the difference was not significant (p = 0.529). Gender distribution was identical (32 males and 16 females in each group, p = 1.000). The mean BMI was also slightly higher in Group A (27.14 vs. 25.38), though not statistically significant (p = 0.542). This ensures adequate randomization and comparability of baseline characteristics.

Table 2. Distribution of Subjects According to Wound Classification

Wound Class	Group A (Conventional)	Group B (NPWT)	p-value
Class I (Clean)	06	05	0.076
Class II (Clean-Contaminated)	22	32	
Class III (Contaminated)	16	11	
Class IV (Dirty/Infected)	04	00	
Total	48	48	

The majority of cases belonged to Class II (Clean-Contaminated), accounting for 54 patients (56.3%). Class III wounds constituted 27 cases (28.1%), Class I wounds

11 cases (11.5%), and Class IV wounds 4 cases (4.2%). Although not statistically significant (p = 0.076), Group A had more Class IV wounds, while Group B had more Class II wounds. This distribution reflects a slightly higher wound risk profile in the conventional dressing group.

Table 3. Postoperative Wound Complications on Day 4

Complication	Group A (Conventional)	Group B (NPWT)	p-value
Surgical Site Infection (SSI)	01	00	0.315
Seroma	04	00	0.041*
Hematoma	01	00	0.315
Wound Dehiscence	00	00	–
Delayed Healing	00	00	–

On Day 4, early wound complications were observed predominantly in Group A. Seroma formation was significantly higher in Group A (4 cases) compared to none in Group B (p = 0.041). Single cases of SSI and hematoma were reported in Group A, while no such complications occurred in the NPWT group. No wound dehiscence or delayed healing was recorded at this stage. These findings suggest that NPWT provides early protection against fluid accumulation.

Table 4. Postoperative Wound Complications on Day 7

Complication	Group A (Conventional)	Group B (NPWT)	p-value
Surgical Site Infection (SSI)	11	02	0.007*
Seroma	02	00	0.153
Hematoma	00	00	–
Wound Dehiscence	01	00	0.315
Delayed Healing	06	00	0.011*

By Day 7, wound complications were significantly higher in Group A. SSI occurred in 11 patients (22.9%) in Group A versus only 2 patients (4.2%) in Group B (p = 0.007). Delayed wound healing was also seen exclusively in Group A (6 cases, p = 0.011). Minor complications such as seroma and wound dehiscence occurred only in Group A, but without statistical significance. These results clearly highlight the preventive role of NPWT in reducing infections and promoting timely healing.

Table 5. Comparison of Postoperative Hospital Stay

Group	Mean ± SD (days)	Median	Range	p-value
Group A (Conventional)	3.79 ± 0.85	4.00	3–6	<0.001*
Group B (NPWT)	2.23 ± 0.52	2.00	2–4	

The mean postoperative hospital stay was significantly shorter in the NPWT group (2.23 days) compared to the conventional dressing group (3.79 days, p < 0.001). This demonstrates that NPWT not only reduces complications but also accelerates recovery, leading to earlier discharge and reduced healthcare burden.

Table 6. Final Wound Healing Outcome

Final Outcome	Group A (Conventional)	Group B (NPWT)	p-value
Healed	30	46	<0.001*
Complicated	18	02	
Total	48	48	

At final follow-up, complete wound healing was observed in 46 patients (95.8%) in Group B compared to only 30 patients (62.5%) in Group A. Conversely, complications were more frequent in Group A (18 cases, 37.5%) compared to just 2 cases (4.2%) in Group B. The difference was highly significant (p < 0.001), firmly establishing the clinical efficacy of short-term prophylactic NPWT in improving wound outcomes.

DISCUSSION

This prospective observational study evaluated the efficacy of three-day prophylactic negative pressure wound therapy (NPWT) compared to conventional gauze dressings in patients undergoing midline laparotomy. The findings demonstrated a significant reduction in postoperative wound complications—including seroma, surgical site infection (SSI), and delayed healing—in the NPWT group. Moreover, the final wound healing rates and hospital stay durations were notably more favourable in the NPWT group compared to conventional management.

On postoperative Day 4, early complications such as seroma formation were exclusively observed in the conventional dressing group (8.3%), whereas none were reported in the NPWT group. By Day 7, the SSI rate in the NPWT group was significantly lower (4.2%) compared to the conventional group (22.9%). Additionally, delayed healing was observed in 12.5% of the conventional group but was absent in the NPWT cohort. The final wound healing rate was significantly better in patients managed with NPWT (95.8% vs. 62.5%), underscoring the superiority of NPWT in both early and long-term wound outcomes.

These results are consistent with the study by Li et al., who reported a significant reduction in superficial SSIs from 23.7% in the control group to 3.0% with NPWT, particularly beneficial for incisions exceeding 20 cm in length.[18] Similarly, De Vries et al. reported a dramatic reduction in incisional SSI rates from 48% to 7% following NPWT in complex abdominal wall repairs.[19] Maharjan et al. also observed significant reductions in SSI (28.5% vs. 5.8%), seroma (18.5% vs. 7.2%), and delayed healing with NPWT, findings that closely align with our results.[20]

Bhatt et al. demonstrated a significantly higher SSI rate in the control group post-emergency laparotomy ($p < 0.001$), reinforcing the role of NPWT in high-risk abdominal surgeries.[21] Cagney et al. reported reduced seroma formation (18% vs. 6%) and wound dehiscence with NPWT.[22] These outcomes mirror our findings of zero incidence of seroma and dehiscence in the NPWT arm. Shiroky et al. observed an overall 39% reduction in SSI risk, with concurrent declines in seroma and dehiscence, further validating the clinical benefits of NPWT.[23]

AbdelDayem et al., using a protocol similar to the present study (3-day NPWT), documented a significant reduction in SSI (24.3% vs. 4.2%) and reported zero cases of delayed healing in the NPWT group.[24] Wells et al. also noted decreased superficial SSI (11.3% vs. 6.3%) and indirectly improved healing outcomes with NPWT.[25] Norman et al. conducted a meta-analysis indicating moderate-certainty evidence for SSI reduction (RR = 0.73) with NPWT, although no significant impact on dehiscence was observed.[26]

Fowler and Barry reviewed a broad range of studies and confirmed the consistent effectiveness of NPWT in reducing SSIs across high-risk surgical populations.[27] Moreno Gijón et al. provided strong evidence for NPWT in reducing complications and shortening hospital stay (OR = 0.31), a benefit replicated in our study where the NPWT group had a significantly shorter mean hospital stay.[28] Lastly, Costa et al. demonstrated that both PICO and Prevena NPWT systems significantly reduced SSIs and surgical site occurrences, further supporting NPWT's superiority over conventional dressings in emergency abdominal surgeries.[29]

Despite the robust findings, this study has certain limitations. It was conducted at a single tertiary care institution, which may limit the generalizability of results to other settings or surgical populations. The sample size, though adequate for statistical analysis, remains relatively small for definitive subgroup assessments. Additionally, blinding of outcome assessment was not feasible due to the nature of the intervention, which may introduce observer bias. Finally, while the follow-up period was sufficient to capture early wound complications, longer-term outcomes such as incisional hernia formation or chronic wound issues were not assessed. Future multicentric randomized controlled trials with larger sample sizes and extended follow-up are warranted to validate these findings and establish standardized NPWT protocols for routine surgical care.

CONCLUSION

The present study demonstrates that short-duration prophylactic negative pressure wound therapy (NPWT) is significantly more effective than conventional gauze dressing in reducing postoperative wound complications after midline laparotomy. Patients in the NPWT group experienced markedly lower rates of surgical site infection, seroma, and delayed wound healing, along with a significantly shorter duration of hospital stay.

The majority of patients managed with NPWT achieved complete wound healing, highlighting its superiority over conventional dressings. By improving wound outcomes and reducing hospital burden, NPWT offers a simple, effective, and resource-efficient strategy for enhancing recovery in patients undergoing abdominal surgery.

Conflict of Interest

The authors declare no conflict of interest related to this study.

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Availability of data and materials: Data will be available by emailing pritipadiyar@gmail.com

Authors' Contributions:

Author1*: participated in the investigation, conceptualization, methodology, resources, validation, writing, reviewing, and editing.

Author2: corresponding author participated in data collection, writing, reviewing, and editing.

Author3: participated in the investigation, conceptualization, writing, review, data collection, and editing.

Author4: corresponding author participated in data collection, writing, reviewing, supervision and editing.

Author5: corresponding author participated in data collection, writing, reviewing, and editing.

All authors have read and agreed to the published version of the manuscript. All authors have read the final manuscript.

Ethics approval and consent to participate: The research adhered to the ethical principles outlined in the Declaration of Helsinki (2013). Approval for the study protocol was granted by the SMS Medical College Ethics Committee, with a decision number of **MC/EC/66/2023** in 2023. Electronic signatures were obtained as informed consent from all individual participants involved in the study. Every procedure conducted during the study complied with the standards of Institutional Ethics Committee and aligned with the principles set forth in the 1964 Helsinki Declaration, along with its subsequent amendments.

Competing Interest: The authors declare that they have no competing interests.

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Original Article

Clinical Outcomes of Laser Ablation Surgery for Pilonidal Sinus Disease: A Prospective Observational Study at a Tertiary Care Center in North India

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ABSTRACT

Background: Pilonidal sinus disease (PSD) predominantly affects young adults and is known for its high recurrence rates and postoperative morbidity with conventional surgical methods. Laser ablation, a minimally invasive alternative, has shown promise in recent literature, but data from public healthcare settings in India remain limited.

Methods: This prospective observational study included 40 patients aged 18–60 years with clinically diagnosed uncomplicated PSD, conducted at SMS Medical College and Hospital, Jaipur, from January to December 2024. All patients underwent sinus laser-assisted closure using a 1470-nm radial diode laser fiber. Primary outcome measures included operative time, postoperative pain (VAS score), hospital stay, time to resume daily activities, complications, recurrence at 3 and 6 months, patient satisfaction, and cosmetic results.

Results: The mean age of patients was 25.95 ± 5.72 years, with 90% being male. The average operative time was 17.8 ± 4.87 minutes. Postoperative pain (VAS score) decreased significantly from a mean of 3.45 (immediate post-op) to 0.58 (Day 15). Most patients (70%) resumed routine activities within 4–6 days. Recurrence occurred in 3 patients (7.5%) at both 3 and 6 months. Two patients (5%) developed minor infections. The mean satisfaction score was 3.93 out of 5, with nearly half reporting good to excellent cosmetic outcomes.

Conclusion: Laser ablation is a safe, rapid, and effective modality for the treatment of uncomplicated pilonidal sinus disease. It offers favourable postoperative outcomes, low complication rates, and high patient satisfaction, making it a viable alternative to conventional surgical techniques, particularly in resource-limited public healthcare settings.

Keywords: Pilonidal sinus, laser ablation, minimally invasive surgery, recurrence, VAS score, day-care surgery, diode laser, India.

INTRODUCTION

Pilonidal sinus disease (PSD) is a chronic, recurrent condition primarily affecting the sacrococcygeal region in young, hirsute males.[1] Derived from Latin *pilus* (hair) and *nidus* (nest), it typically involves sinus tracts containing hair within the natal cleft.[2] Clinically, PSD presents with pain, swelling, seropurulent discharge, and abscesses.[3] Though once considered congenital, current understanding supports an acquired origin due to hair shaft penetration and a foreign body inflammatory response.[4]

PSD has a notable global burden, affecting about 26 per 100,000 people, with incidence varying regionally (0.07–0.25%).[5] In India, national prevalence is under-reported, but hospital data show ~1.1% incidence among young adults,[6] with tertiary centers like SMS Medical College managing 200–250 cases annually. Most patients present late due to recurrence, poor awareness, or delayed diagnosis.

The disease commonly affects individuals aged 15–35, peaking between 20–30 years, with a male-to-female ratio of 3–4:1.[7–8] Risk factors include sedentary lifestyle, obesity, deep clefts, poor hygiene, and certain occupations (e.g., barbers, drivers).[9–10]

Conventional treatments include incision and drainage, excision with secondary healing or primary closure, and flap techniques.[11] However, recurrence rates remain high (up to 30%) due to midline closure, incomplete tract removal, or postoperative complications.[12]

Minimally invasive laser therapies like SiLaC, SiLaT, PiLaT, and LEPSiT use radial diode lasers for targeted ablation of sinus tracts.[13] These techniques offer faster recovery, less pain, minimal scarring, and better cosmetic outcomes.[14] European studies report <24-hour hospital stays in 92% of cases and recurrence rates around 8.3%.[15] Laser-treated patients also show significantly lower postoperative pain and quicker return to work compared to open surgery.[16–17]

Despite global uptake, Indian data on laser therapy in PSD are sparse, especially from public institutions. This study aims to evaluate the outcomes of laser ablation in PSD patients at SMS Hospital, Jaipur, focusing on recurrence, VAS pain scores, operative time, and return to normal activities. Findings may support broader adoption of minimally invasive approaches in public healthcare settings.

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MATERIAL & METHODS

This prospective observational study was conducted in the Department of General Surgery, S.M.S. Medical College and Attached Hospitals, Jaipur, Rajasthan, India, over a period of 12 months from January 2024 to December 2024.

The study included patients aged between 18 and 60 years who were clinically diagnosed with uncomplicated pilonidal sinus disease and scheduled for elective laser ablation surgery. Only patients with midline, non-infected sinuses and no prior history of surgical intervention for PSD were included. Patients with acutely inflamed or infected sinuses, complex tracts with multiple secondary openings, prior PSD surgery, uncontrolled systemic comorbidities (e.g., diabetes, chronic renal or liver disease), immunocompromised status (e.g., HIV or immunosuppressive therapy), or those unable to comply with follow-up protocols were excluded.

All patients underwent a detailed clinical evaluation including history, physical examination, and assessment of sinus tract characteristics such as location, number of openings, and presence of discharge. Tract length was documented intraoperatively. The diagnosis of pilonidal sinus was confirmed clinically. Pain severity was assessed using the Visual Analogue Scale (VAS) immediately postoperatively, and on days 7 and 15.

All surgical procedures were performed under local or spinal anesthesia depending on patient suitability. A 1470-nm radial diode laser fiber was used to deliver photothermal energy through the primary opening of the sinus tract. The laser energy was applied circumferentially along the tract to ablate the epithelial lining and induce tract closure. No suturing was required, and the procedure was completed in a minimally invasive fashion.

Postoperative care included analgesics, local wound care, and routine discharge instructions. Patients were followed up on postoperative days 7 and 15, and subsequently at 3 months and 6 months. At each follow-up visit, VAS scores were recorded, the surgical site was examined for healing or complications, and recurrence was assessed clinically. Recurrence was defined as the presence of new sinus openings, discharge, or signs of infection at the operated site.

Additional outcome parameters included duration of surgery, length of hospital stay, time taken to return to normal activities, patient satisfaction (on a 5-point Likert scale), and cosmetic outcomes as assessed by the operating surgeon. Any intraoperative or postoperative complications, including infection, hematoma, or delayed healing, were also documented.

Data were compiled and analyzed using Microsoft Excel and SPSS software version 25.0. Descriptive statistics were used to summarize demographic and clinical data. Pain scores at different time intervals were compared using paired t-tests or Wilcoxon signed-rank tests, depending on data distribution. A p-value of <0.05 was considered statistically significant.

RESULTS

Table 1: Demographic and Clinical Profile of Patients (n = 40)

Variable	Category	Number (%)
Age Group (Years)	18–30	35 (87.50%)
	31–40	04 (10.00%)
	41–50	01 (02.50%)
	Mean ± SD	25.95 ± 5.72
Gender	Male	36 (90.00%)
	Female	04 (10.00%)
Sinus Tract Location	Midline	40 (100.00%)
	Off-midline	00 (00.00%)
Family History of PSD	Yes	20 (50.00%)
	No	20 (50.00%)
Number of Openings	1	12 (30.00%)
	2	15 (37.50%)
	≥3	13 (32.50%)

This table summarizes patient demographics and disease characteristics. Most patients were young adult males with midline sinus tracts. Half reported a positive family history, and nearly one-third had multiple sinus openings, indicating chronic disease.

Table 2: Pain Progression Based on VAS Scores Over Time

VAS Score (Time Point)	VAS Range	Number of Patients (%)	Mean ± SD
Immediate Post-Op	0–3	22 (55.00%)	3.45 ± 0.75
	4–6	18 (45.00%)	
Day 7	0–1	20 (50.00%)	1.48 ± 0.96
	2–3	20 (50.00%)	
Day 15	0	23 (57.50%)	0.58 ± 0.78
	1–2	16 (40.00%)	
	≥3	01 (02.50%)	

There was a marked reduction in pain scores from immediate postoperative to Day 15. Most patients were pain-free or experienced minimal discomfort by the end of the second postoperative week, indicating rapid recovery.

Table 3: Surgical Recovery and Return to Routine Activities

Parameter	Category	Number (%)	Mean ± SD
Hospital Stay	1 Day	22 (55.00%)	1.45 ± 0.50
	2 Days	18 (45.00%)	
Return to Work	≤3 Days	08 (20.00%)	4.73 ± 1.24
	4–6 Days	28 (70.00%)	
	>6 Days	04 (10.00%)	

Laser ablation allowed early discharge and return to normal activities. Over 70% of patients resumed routine work within 4–6 days postoperatively, supporting the feasibility of laser treatment as a day-care surgical option.

Table 4: Recurrence and Postoperative Complications

Outcome	Time Point	Number (%)
Recurrence	At 3 Months	03 (07.50%)
	At 6 Months	03 (07.50%)
Postoperative Infection	Overall	02 (05.00%)
Intraoperative Complications	None	00 (00.00%)

Low recurrence and complication rates were observed. No intraoperative complications occurred, and only two cases of minor postoperative infection were documented, confirming the safety and effectiveness of the procedure.

Table 5: Operative Time, Patient Satisfaction, and Cosmetic Outcome

Parameter	Category	Number (%)	Mean ± SD
Operative Time	<15 minutes	11 (27.50%)	17.80 ± 4.87
	15–20 minutes	18 (45.00%)	
	>20 minutes	11 (27.50%)	
Patient Satisfaction	Score 3	16 (40.00%)	3.93 ± 0.86
	Score 4	11 (27.50%)	
	Score 5	13 (32.50%)	
Cosmetic Outcome	Excellent	09 (22.50%)	—
	Good	10 (25.00%)	
	Fair	11 (27.50%)	
	Poor	10 (25.00%)	

The average operative time was under 20 minutes for most patients. High satisfaction and acceptable cosmetic outcomes were reported, further reinforcing laser ablation as a preferred minimally invasive modality for PSD.

DISCUSSION

This study evaluated the outcomes of laser ablation surgery in 40 patients with uncomplicated pilonidal sinus disease (PSD) at a tertiary care government hospital in North India. The findings reaffirm the growing consensus that laser ablation is a safe, efficient, and patient-friendly modality for treating PSD, particularly in young adults.

The mean age of the study participants was 25.95 years, with 87.5% of patients falling in the 18–30 years age group. This supports the well-established epidemiological trend that PSD is primarily a disease of young adults, particularly males. Our sex distribution (90% male) is consistent with existing literature highlighting male predominance due to risk factors such as dense hair, deep gluteal cleft anatomy, and prolonged sitting. Similar age and gender patterns were reported in studies by Romic et al.[18], De Decker et al.[19], and Li et al.[20].

A family history of PSD was observed in 50% of cases, underlining the potential genetic predisposition to disease development. This aligns with the findings of Lukish et al.[21], who noted familial clustering in adolescents, and Ganduboina et al.[22], who emphasized genetic traits like hair texture and gluteal anatomy as risk factors.

In terms of disease complexity, 37.5% of patients had two sinus openings, while 32.5% had three or more, suggesting chronic or recurrent sinus formation. Demir et al.[23] found that a greater number of external openings was associated with higher recurrence and poor healing outcomes, supporting our inclusion of only uncomplicated cases for consistent comparison.

All sinuses in our cohort were located midline—typical for PSD—making them ideal candidates for laser ablation. Studies such as Iesalnieks et al.[24] and Sluckin et al.[25] have stressed that midline tracts respond favourably to laser therapy compared to traditional midline closure surgeries, which carry higher recurrence risks.

Pain resolution was rapid and significant in our study. The mean VAS score declined from 3.45 immediately post-op to 1.48 on Day 7 and 0.58 on Day 15. These results mirror those of Yardimci et al.[26], who found significantly lower postoperative pain scores in laser-treated patients compared to those undergoing conventional Karydakis flap surgery. Similarly, Sluckin et al.[25] and Emral et al.[27] reported reduced analgesic requirements and faster pain relief in their laser groups.

The average operative time in our study was 17.8 minutes, which is comparable to findings by Li et al.[20] (mean: 15.5 minutes) and Yardimci et al.[26] (mean: 15.1 minutes). This reflects the procedural efficiency of laser ablation, especially in non-complicated sinuses. In contrast, traditional flap techniques such as Karydakis or Limberg require 30–60 minutes on average, as highlighted by Tyrväinen et al.[28].

Hospital stay was minimal, with 55% discharged within 24 hours and the rest within 48 hours. A rapid return to routine activities (mean: 4.73 days) was also observed. These findings are consistent with reports by Williams et al.[29] and Romanova et al.[30], where most patients resumed normal life within a week, reinforcing laser ablation's suitability for day-care surgery.

Recurrence was observed in only 7.5% of patients at both 3 and 6 months, which compares favourably with traditional excision methods. For instance, Horesh et al.[31] reported recurrence rates of 8.2% with adjunct laser therapy versus 32.9% in trephine-only surgery. Xie et al.[32], in a meta-analysis, found an average recurrence of 7.6%

across over 1200 patients, echoing our findings. Additionally, Romic et al.[18] reported a recurrence rate of 3.8%, while Gülen et al.[33] documented 8.3%.

Only two cases (5%) developed postoperative infection, and no intraoperative complications were reported. These low complication rates are supported by studies like Li et al.[20] and Ganduboina et al.[22], which emphasize the sterile and minimally invasive nature of laser techniques.

Patient satisfaction was notably high, with a mean satisfaction score of 3.93 out of 5. Cosmetic results were rated as excellent or good in nearly half the patients. These outcomes are in line with reports by Sluckin et al.[25] and Emral et al.[27], who highlighted superior aesthetic results and positive patient-reported outcomes with laser therapy.

Overall, our results reaffirm that laser ablation is a practical and effective solution for pilonidal sinus management, particularly in young patients with uncomplicated disease. It significantly reduces postoperative pain, operative time, hospital stay, and recurrence, while ensuring rapid recovery and high patient satisfaction. Although flap surgeries may still be necessary for complex or recurrent cases, laser ablation offers clear advantages for first-line management in select patient groups

CONCLUSION

Laser ablation surgery using a 1470-nm radial diode fiber is a safe, efficient, and minimally invasive treatment option for uncomplicated pilonidal sinus disease. This study demonstrates that laser ablation offers significant advantages, including reduced postoperative pain, shorter operative time, minimal hospital stay, early return to normal activities, low recurrence rate, and high patient satisfaction. These benefits, coupled with the cosmetic appeal and feasibility in day-care settings, make laser ablation a promising first-line option, especially in young adults. Further multicenter randomized controlled trials with longer follow-up are recommended to validate these findings and expand its indications to more complex or recurrent cases.

Conflict of Interest

The authors declare no conflict of interest related to this study.

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Availability of data and materials: Data will be available by emailing drdebaratibanerjee@gmail.com

Authors' Contributions:

Author1*: participated in the investigation, conceptualization, methodology, resources, validation, writing, reviewing, and editing.

Author2: participated in the investigation, conceptualization, writing, review, data collection, and editing.

Author3: corresponding author participated in data collection, writing, reviewing, and editing.

Author4: corresponding author participated in data collection, writing, reviewing, and editing.

All authors have read and agreed to the published version of the manuscript. All authors have read the final manuscript.

Ethics approval and consent to participate

The research adhered to the ethical principles outlined in the Declaration of Helsinki (2013). Approval for the study protocol was granted by the SMS Medical College Ethics Committee, with a decision number of **MC/EC/2023/406** in 2023. Electronic signatures were obtained as informed consent from all individual participants involved in the study. Every procedure conducted during the study complied with the standards of Institutional Ethics Committee and aligned with the principles set forth in the 1964 Helsinki Declaration, along with its subsequent amendments.

Competing Interest: The authors declare that they have no competing interests.

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Case Report

Iniencephaly Clausus With Acrania, Cervical Myelocystocele And Cervicodorsal Rachischisis In Fetus: A Unique Case Of Triple Neural Tube Defects

Mukesh Mittal*, Anupam Rajoria*, Sumit Kumar Patidar*

ABSTRACT

Iniencephaly is a rare and fatal neural tube defect and triple neural tube defects are rarer. Only five cases of triple neural tube defects have been reported worldwide till date and this case is a unique case of triple neural tube defect having specific anomalies of iniencephaly clausus with acrania, cervical myelocystocele and cervicodorsal rachischisis in fetus. we report the case of a 30 years old female who came to our tertiary care hospital for first antenatal scan. There was no history of folic acid supplementation in this pregnancy. Ultrasound revealed single live intrauterine fetus of 20 weeks with frog eye appearance suggesting partial acrania, short and deformed occiput and cervical vertebrae showing fixed retroflexion of head or star gazing appearance, cystic lesion with neural contents in subcutaneous posterior cervical region protruding from vertebral defect suggestive of myelocystocele along with complete multilevel splaying of cervicothoracic spine without skin covering suggesting rachischisis. No other anomaly was associated with this in this fetus. This was a unique case of triple neural tube defect having Iniencephaly clausus with partial acrania, cervical myelocystocele and cervicodorsal rachischisis in fetus. On counselling to the family about the poor postnatal prognosis, family decided to terminate the pregnancy and findings were confirmed in the fetus after medical termination of pregnancy. The case highlights the importance of planned folic acid supplementation in pregnancy, timely prenatal imaging in detecting congenital complex neural tube defects and family counselling for medical termination of pregnancy to reduce maternal trauma.

Keywords: Iniencephaly, Myelocystocele, Rachischisis, acrania, Neural Tube Defects, Antenatal ultrasound

INTRODUCTION

While neural tube defects are common congenital anomalies, iniencephaly is one of the uncommon and more severe neural tube defects with incidence ranging from 0.01 to 1 in 1000 pregnancies. It is characterized by occipital bone defect, partial or total absence of cervicothoracic vertebrae (rachischisis) and fixed fetal head retroflexion.[1] The iniencephaly clausus is characterized by the absence of an encephalocele while iniencephaly apertus is characterized by the Iniencephaly with an encephalocele.[2] The exact etiology and pathogenesis of iniencephaly are not known, however both genetic and environmental causes have been implicated. Iniencephaly may be associated with other congenital anomalies including anencephaly and other systemic abnormalities.[2]

Myelocystocele is a closed spinal dysraphism which is uncommon and more frequently found in terminal spine.[3] Cervical myelocystoceles are rarely reported.[4]

The existence of multiple neural defects at different locations in the same fetus is uncommon and very few cases have been found in world literature. A triple neural tube defect in a fetus is rarer. Only five cases of triple neural tube defects have been reported worldwide till date and this case is a unique case of triple neural tube defect having specific anomalies of iniencephaly clausus with acrania, cervical myelocystocele and cervicodorsal rachischisis in fetus.[5]

CASE REPORT

A 30-year-old gravida 4 para 3 patient reported for her first routine antenatal ultrasound scan in the radiodiagnosis department in our tertiary care hospital. There was no history of folic acid supplementation, congenital anomaly in previous pregnancies, strong consanguinity, prior comorbidity, smoking or any drug intake. Ultrasound scan revealed single live intrauterine fetus of 20 weeks pregnancy with partial absence of skull vault giving a frog eye appearance, along with short and deformed occipital bone and cervical vertebrae causing fixed retroflexion of head, corresponding to the description of a star gazing fetus [Figure 1]. In addition, there was a skin covered cystic lesion showing neural elements that was protruding from the vertebral defects in subcutaneous posterior cervical region suggestive of myelocystocele. There was also long segmental splaying of posterior cervicothoracic spine without skin covering corresponding with description of rachischisis. There were no associated renal, cardiac, gastrointestinal or other anomalies in the fetus. Amniotic fluid index was on higher side but maternal alpha-fetoprotein (AFP) levels were within normal limits.

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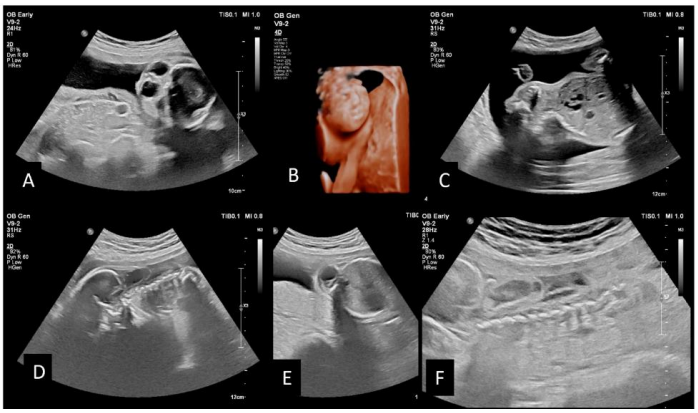

Figure 1: Antenatal USG images of live intrauterine fetus at 20 weeks of gestation showing in (A): frog eye appearance, (B): 3 D USG with partial acrania and retroflexed head, (C): retroflexed head and short neck causing abnormal coronal view, (D): deficient occipital bone and cervical vertebrae with cystic outpouching in the back, (E): splayed posterior elements of spine and cystic lesion covered with skin, (F): representative image of multiple neural tube defects showing myelocystocele (thick arrow) and rachischisis (curved arrow).

After counselling of parents regarding the poor prognosis of fetus, termination of pregnancy was performed vaginally through medical induction by prostaglandins. The patient and her family had refused further imaging with MRI. Genetic counselling was not done as it was not available in our institute and fetal autopsy was refused. The antenatal imaging findings were confirmed in the fetus after delivery [Figure 2].

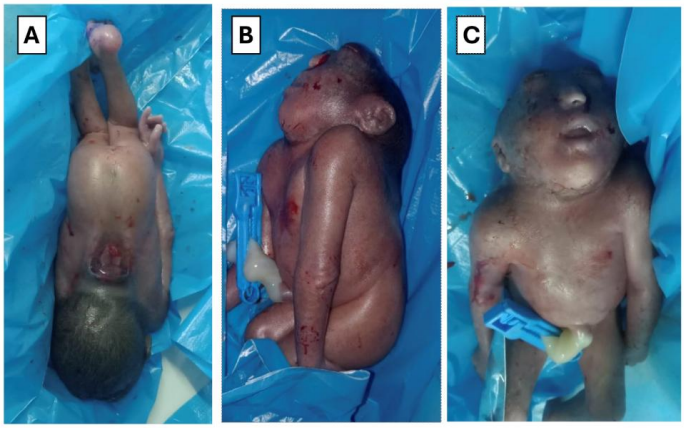

Figure 2. Fetus delivered after termination of pregnancy. A: Back shows absence of encephalocele, subcutaneous cervical mass and more inferiorly open spina bifida with exposed spinal tissue; B: Side view shows partial acrania, retroflexed head and subcutaneous cervical mass (myelocystocele); C: Frontal view shows retroflexed head position (star gazing).

DISCUSSION

While environmental and nutritional factors are implicated in causation of neural tube defects, chromosomal abnormalities including trisomy 18, trisomy 13 and monosomy X are also associated.[2] Risk factors include poor nutrition, lack of folic acid, obesity, and exposure to certain medications (such as sulphonamides, tetracyclines, and antihistamines).[6] In our case there was no history of folic acid supplementation, which is well known to impart a protective effect.[7] Characteristic features of Iniencephaly are short or absent neck, retroflexion of head, occipital bone defect and defect in cervical and thoracic vertebrae. On ultrasound, this gives the fetus a characteristic "stargazing" appearance.[6] Iniencephaly may be associated with other congenital anomalies such as anencephaly, encephalocele, meningomyelocele, hydrocephalus, Dandy-Walker malformation, holoprosencephaly, gastrointestinal atresia, omphalocele, congenital diaphragmatic hernia, polycystic kidneys, hydronephrosis, caudal regression sequence, arthrogryposis, clubfoot, single umbilical artery and cardiac defects.[2]

Our case demonstrated deficient anterior calvarium lending the frog eye appearance with presence of posterior skin covered cranial vault, suggesting partial acrania. Cervical cystic lesion containing neural elements was covered with skin, conferring a diagnosis of cervical myelocystocele, a rare entity in itself. Thus, our case showed iniencephaly accompanied by cervicothoracic rachischisis as well as partial acrania and cervical myelocystocele, making it a unique case of triple neural tube defects. The presence of triple neural tube defects at multiple sites as in our case favors the multi-site closure theory.[5]

In one study, contrary to findings in our case, elevated maternal and amniotic fluid alpha-fetoprotein (AFP) levels were associated, and polyhydramnios was present in 75% of the cases.[1] Iniencephaly should be distinguished from similar conditions like anencephaly, Klippel-Feil syndrome, and neck tumors. Abnormal vertebrae with head covered with skin is a characteristic feature of iniencephaly, which is not a feature of anencephaly. Klippel-Feil syndrome may show fused vertebrae, but without the fixed head retroflexion seen in iniencephaly.[8]

This condition often leads to obstructed labor due to the abnormal fetal posture and has a high recurrence risk in future pregnancies. Given its universally fatal outcome, termination is considered a justified option when diagnosed.[9]

CONCLUSION

Iniencephaly, a rare fatal defect of neural tube development due to defective neural tube closure.

The existence of multiple neural defects at different locations in the same fetus is rarer. This is a unique case of triple neural tube defect with specific anomalies of iniencephaly clausus with acrania, cervical myelocystocele and cervicodorsal rachischisis in fetus.[5] This case call attention to routine antenatal supplementation of folic acid, routine antenatal sonography for diagnosis of complex neural tube defects and counselling to the parents for the

medical termination of pregnancy to reduce maternal trauma.

Abbreviations
USG: Ultrasonography
3D USG: 3 Dimensional Ultrasonography
AFP: Alpha-fetoprotein
MRI: Magnetic Resonance Imaging

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Authors' Contributions
Author1: participated in the investigation, conceptualization, methodology, resources, supervision, validation, writing, reviewing, and editing.
Author2 and corresponding author: participated in the investigation, conceptualization, writing, review and editing.
Author3: participated in data collection, writing and reviewing.

All authors have read and agreed to the published version of the manuscript. All authors have read the final manuscript.

Ethics approval and consent to participate
This case report has been conducted in accordance with the principles outlined in the Declaration of Helsinki. Informed consent was obtained from the patient for the publication of their clinical information and any accompanying images. Confidentiality has been maintained throughout the manuscript, with all identifiers removed to protect the patient's privacy.

Competing Interest
The authors declare that they have no competing interests.

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Case Report

Image-Guided Management of Retained Placenta In A Case Of Placenta Accreta: A Case Report Of An Obstetric Emergency

Mukesh Mittal*, Anupam Rajoria*, Prafull Singhal *, Shri Ram Yadav*

ABSTRACT

Background: Placenta accreta is a serious obstetric condition characterized by abnormal adherence of the placenta to the myometrium, often leading to retained placenta and life-threatening hemorrhage and may require hysterectomy. Missed retained placenta can present later more frequently in cases with placentomegaly.

Case Summary: We present a case of a diabetic and hypertensive 32-year-old woman with a history of prior caesarean section, who presented at 25 weeks of gestation with severe preeclampsia and signs of placental insufficiency. Termination of pregnancy was done in view of significant risk to maternal health and less chances of reaching fetal viability. While placenta accreta had not been suspected in previous sonography, imaging prior to discharging the patient revealed a retained placental mass suggestive of retained placenta accreta. As patient was asymptomatic and clinically stable without bleeding per vagina, patient was not surgically intervened. A conservative management approach was adopted under close clinical and radiological monitoring using systemic Intramuscular Methotrexate (1 mg/kg). One week after first dose, manual evacuation of retained placenta was attempted but sonography showed a retained placental tissue. Treatment continued and a small mass reportedly passed per vagina. Follow-up ultrasounds demonstrated complete disappearance of the placental tissue with decrease in beta-hCG levels after two weeks.

Conclusion: This case underscores the importance of pre-discharge imaging in cases with increased possibility of placentomegaly and placenta accreta that undergo abortion or delivery. We highlight the utility of conservative medical management in select cases of retained placenta to spare the uterus and preserve fertility.

Keywords: Placenta accreta, placentomegaly, pre-eclampsia, retained placenta, methotrexate, conservative management, ultrasound.

INTRODUCTION

Placenta accreta is a life-threatening condition caused by abnormal placental adherence to the myometrium due to defective decidua basalis. Placenta that remains after abortion or term delivery can presents like persistent bleeding, pelvic pain, sepsis and gestational trophoblastic reaction. [1]

Major risk factors include prior cesarean sections, placenta previa, uterine surgery, advanced maternal age, and multiparity [2]. Chorionic villi invade the myometrium, increasing the risk of postpartum hemorrhage, retained placenta, and sepsis if not managed appropriately. Retained placenta may be missed more frequently in cases of placentomegaly, and may present later with heavy uterine bleeding or gestational trophoblastic reaction. [3] Various surgical and medical methods adopted in treatment of retained placenta. Most used surgical method is dilation and curettage. Medical management for retained placenta is by systemic Intramuscular Methotrexate (1 mg/kg). [4]

Early diagnosis significantly improves outcomes and reduces the likelihood of hysterectomy. Imaging modalities such as ultrasonography (USG) and magnetic resonance imaging (MRI) are critical in diagnosis. Sonographic findings include myometrial thinning, loss of hypoechoic zone under placental bed, increased placental lacunae, hypervascularity and placental bulge into adjacent structures.

CASE PRESENTATION

A 32-year-old woman, G2P1L1A0, with a previous cesarean section and known case of diabetes mellitus and hypertension (on treatment for 10 years), presented at 25 weeks of gestation with complaints of bilateral leg swelling, reduced fetal movement for 3 days, and vaginal bleeding for 1 day.

On general physical examination blood pressure of patient was 180/100 mmHg her abdomen was mildly distended and uterus was relaxed with normal contour. Antenatal USG showed a single live intra uterine fetus at 25 weeks with features of placental insufficiency in the form of absent flow in the umbilical artery along with oligohydramnios. Bilateral mild fetal hydronephrosis was also noted and placenta was posterior and upper. Her blood sugar level was 210 gm/dl.

In view of significant risk to maternal health and less chances

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of reaching to fetal viability, a decision was taken by the concerned parties to proceed for termination of pregnancy, and induction of premature delivery was performed after taking an informed written consent of family. The demised fetus and placenta were reportedly delivered completely per vaginally. Uterus was well contracted and there was no post-partum bleeding.

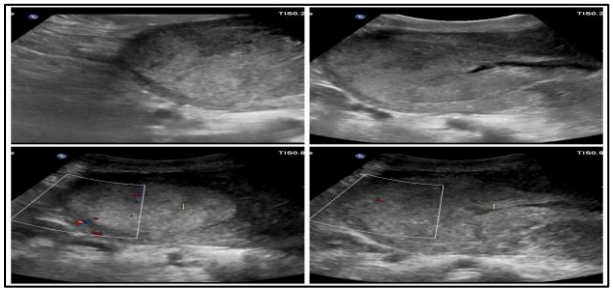
In the post-delivery evaluation on day 5, a routine ultrasound prior to discharge revealed a 7x3 cm echogenic heterogeneous mass attached to the uterine fundus with increased vascularity and associated fundal myometrial thinning, suggesting retained invasive placental tissue. [Figure 1]

Since the patient was hemodynamically stable and very young age, a conservative medical management was planned to preserve the fertility. Intramuscular Methotrexate 1 mg/kg was administered. Regular monitoring was done which included beta-hCG levels, CBC, LFTs, RFTs, and serial ultrasounds.

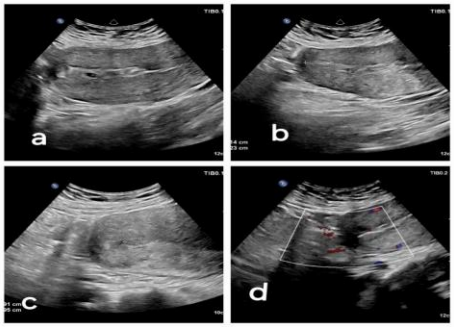
Histopathological examination of the tissue confirmed placental tissue without evidence of dysplastic changes.

One week after first dose of Intramuscular Methotrexate, manual evacuation of retained placenta was attempted but as per post evacuation sonography complete evacuation could not be achieved On Day 10, a follow-up USG showed a portion of placental tissue was seen attached to uterine fundus with mild vascularity.

Treatment continued with systemic Intramuscular Methotrexate (1 mg/kg) and a small mass like structure was passed out per vaginum spontaneously. Follow-up ultrasound on Day 15, demonstrated complete disappearance of the placental tissue with decrease in beta-hCG levels. [Figure 2]



(Figure 1: USG of the pelvis showing retained placenta -Day -5)



(Figure 2: figure a, b and c show USG scan after methotrexate therapy on day-10 and figure 'd' on day 15.)

The patient remained stable with no vaginal bleeding and beta-hCG normalized. She was counselled to avoid conception for one year and advised early USG screening in future pregnancies.

DISCUSSION

The increasing cases of adherent placenta is mainly due to increase in delivery by cesarean section. In cases of placenta previa and prior uterine surgery for myomectomy or history of previous dilatation and curettage, placental adhesion is more common. [5]

Management options include hysterectomy and resuscitation as the first-line treatment in emergency settings [6]. Conservative options including uterine artery embolization, balloon occlusion, and methotrexate therapy [7].

Systemic methotrexate reduces uteroplacental vascularity, promoting gradual resorption of retained placental tissue. However, close monitoring is essential due to risks of infection, sepsis, or delayed hemorrhage. Reported outcomes vary from tissue expulsion within a week to resorption over six months. [8]

Some studies have shown a higher success rate and fewer complications with uterine artery embolization. In patients with focal adherent placenta, management can be removal of placenta by manual extraction by separating the placenta or by surgical excision with repair of resulting defects with uterine preservation. [9]

Ultrasound is the first-line modality, particularly in early second trimester, allowing for timely risk assessment and management planning. MRI is useful for detailed placental mapping in suspected accreta spectrum disorders. It typically reveals heterogeneous placental tissue with focal myometrial thickening and increased vascularity on T2-weighted imaging. In such cases a multidisciplinary approach ensures optimal care involves collaboration between obstetricians, radiologists, neonatologists, and surgeons. Structured screening and antenatal counselling significantly improve perinatal outcomes. [10]

Diabetes mellitus may contribute to placental abnormalities due to oxidative stress and vascular damage. Hypertension impairs placental perfusion and trophoblast invasion, leading to abnormal implantation and placentomegaly with potential accreta formation.

CONCLUSION

This case illustrates the image-guided successful conservative management of retained placenta in a case of placenta accreta using methotrexate in a hemodynamically stable patient. A structured diagnostic approach using imaging and close follow-up is essential for successful conservative management to preserve fertility and to prevent complications of retained placental tissue like persistent bleeding, pelvic pain, sepsis and gestational trophoblastic reaction. Maternal comorbidities such as

diabetes and hypertension further necessitate vigilant monitoring and a routine ultrasound screening is suggested for all patients with diabetes mellitus and hypertension post-delivery before discharging the patients.

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Authors' Contributions
Author*: Conceptualization, methodology, investigation, supervision, validation, writing—original draft and review.
Author**: Corresponding author, Data collection, writing and editing, literature search.
Author***: Patient management, writing, review and editing.
Author****: Data collection, patient management, patient follow up.

All authors have read and approved the final manuscript.

Ethics Approval and Consent to Participate
The research adhered to the ethical principles outlined in the Declaration of Helsinki (2013). Approval for the study protocol was granted by the xxxxxx Ethics Committee, with a decision number of xxx in 202x. Electronic signatures were obtained as informed consent from all individual participants involved in the study. Every procedure conducted during the study complied with the standards of xxxxxx Ethics Committee and aligned with the principles set forth in the 1964 Helsinki Declaration, along with its subsequent amendments.

Competing Interests
The authors declare no competing interests.

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